No. 80-2182

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In The

Supreme Court of the United States

October Term, 1980

INWOOD LABORATORIES, INC., and PREMO PHARMACEUTICAL LABORATORIES, INC.,

Petitioners,

vs.

IVES LABORATORIES, INC.,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

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QUESTIONS PRESENTED

1. Whether the truthful, comparative use of another's trademark in labeling and advertising gives rise to liability for trademark infringement?

2. Whether Section 32 of the Lanham Act (15 U.S.C. §1114) grants a trademark owner monopoly rights in the color of its product?

STATEMENT PURSUANT TO SUPREME COURT RULES 21 AND 28.1

The other parties to the proceeding in the court whose judgment is sought to be reviewed were appellees Darby Drug Co., Inc., MD Pharmaceutical Company, Inc., Rugby Laboratories, Inc., and Sherry Pharmaceutical Co., Inc.

The parent company of petitioner Inwood Laboratories, Inc. is Forest Laboratories, Inc. Petitioner Premo Pharmaceutical Laboratories, Inc. is affiliated with Federal Pharmacal Co.

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PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

OPINIONS BELOW

For convenience, the five opinions rendered below are set forth in the appendices in chronological order.

The first opinion of the District Court, denying respondent's request for preliminary injunctive relief on its primary claims is set forth in Appendix A, and has been officially reported at 455 F. Supp. 939 (E.D.N.Y. 1978)

(hereinafter referred to as *"IVES I"*). The Court of Appeals' decision affirming the District Court's denial of preliminary injunctive relief is set forth in Appendix B, and is officially reported at 601 F. 2d 631 (2d Cir. 1979) (hereinafter *"Ives II"*).

The second opinion of the District Court, dismissing respondent's complaint, is set forth in Appendix C, and is offically reported at 488 F. Supp. 394 (E.D.N.Y. 1980) (hereinafter *"Ives III"*). The opinion of the Court of Appeals at issue herein reversed the District Court and is set forth in Appendix D. It is officially reported at 638 F. 2d 538 (2d Cir. 1981) (hereinafter *"Ives IV"*). A subsequent order by the Court of Appeals denied petitioners' request for rehearing without opinion. The order is not officially reported, and a copy of this order is set forth in Appendix E. Acting on the mandate of the Court of Appeals, the District Court entered an order which, *inter alia*, enjoined petitioners from marketing a drug product in the same capsule colors as those sold by respondent. The memorandum and order are not yet officially reported, and copies are set forth in Appendix F (hereinafter *"Ives V"*).

JURISDICTION

The judgment of the United States Court of Appeals for the Second Circuit, sought to be reviewed herein, was entered on January 8, 1981. Petitioners' subsequent petition for rehearing with suggestion for rehearing *en banc* was denied on February 25, 1981. This Court granted petitioners' request for an extension of time within which to file the instant petition to and including June 25, 1981.

The jurisdiction of this Court is invoked under 28 U.S.C. §1254(1).

CONSTITUTIONAL PROVISIONS AND STATUTES INVOLVED

The constitutional provisions involved herein are Article I, §8, clause 8 of the Constitution of the United States and the First Amendment to the Constitution of the United States. The federal statutory provisions involved herein are §§32 and 43(a) of the Lanham Act, 15 U.S.C. §§1114; 1125(a). The state statutory provisions involved herein are N.Y. Education Law §§6810; 6815(2)(h), (j); 6816; 6816-a (McKinney's Supp. 1981); and N.Y. Public Health Law §206(1)(o) (McKinney's Supp. 1981).

Due to the length of these provisions, they are all set forth in full in Appendix G.

STATEMENT OF THE CASE

At issue in this petition is a ruling by the Court of Appeals which imposes a severe chilling effect on petitioners' First Amendment free speech rights to advertise at the same time as it gives respondent an unprecedented monopolistic advantage. Specifically, the Second Circuit, has now held that manufacturers of generic pharmaceutical products, by reason of truthful comparative advertising and labeling for their products, become subject to liability for contributory infringement under the trademark laws of the United States. The Court of Appeals further held that by virtue of its trademark rights a large brand-name pharmaceutical manufacturer also obtains an automatic monopoly on the "trade dress" of its pharmaceutical products.[1]

1. Trade dress refers to the format one adopts for the packaging and labeling or appearance of goods, as distinguished from a trademark which refers to a name brand applied to the product. *See Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 232 (1964). *See also, Jean Patou, Inc. v. Jacqueline Cochran, Inc.*, 201 F. Supp. 861 (S.D.N.Y. 1962), *aff'd*, 312 F. 2d 125 (2d Cir. 1963).

This ruling, by its very nature, will have critical consequences for the future course of competition in the pharmaceutical industry and the further development of trademark law.

The basic underlying facts of the instant action are relatively simple. Respondent Ives Laboratories, Inc. ("Ives") has been marketing a drug ingredient identified chemically as cyclandelate for many years. Ives sells its cyclandelate product under the registered trademark "Cyclospasmol". Ives sells two dosage forms of this product: a 200-milligram version in a blue capsule, and a 400-milligram version in a blue/red capsule. The drug itself is a "peripheral vasodilator", which is primarily taken by elderly persons to produce an increase in blood flow and thereby inhibit the progressive conditions caused by certain vascular diseases. By law, cyclandelate may be dispensed only on the prescription of a physician. *See generally, Ives III* at 396 (54a).[2]

Until April 26, 1972, Ives had a monopoly on the sale of cyclandelate by virtue of its patent rights.[3] By 1976 however, petitioners Inwood and Premo, among others, had commenced marketing competitive generic equivalents of Ives' product. Petitioners are drug manufacturers who for the most part do not sell directly to dispensing pharmacists but rather to wholesale distributors and hospital pharmacies. Petitioners' generic products were marketed in the same dosage strengths and in the same capsule colors as the Ives product.

In selling their generic product in the same capsule colors as the formerly patented brand-name product, petitioners did not

2. All parenthetical references are to the pages of the attached Appendix, unless otherwise indicated.

3. The generic name "cyclandelate" was used in the United States before respondent used the name "Cyclospasmol" for its cyclandelate product. *See* Osol, Pratt & Altschule, *The United States Dispensatory*, 351 (26th Ed. 1968).

inaugurate a new practice. As expressly found by the District Court, the historic utilization of a similar appearance for generic pharmaceutical products is an important, if not critical, factor in the commercial ability of the generic manufacturers to compete with brand-name companies. *See Ives III* at 398-399 (63a-64a). In this case, the elements of the commercial need to utilize the same colors were found to consist of the following:

(1) Many patients, particularly elderly patients, associate the appearance of a medication with its therapeutic effect. Therefore, some patients refuse to accept equivalent drugs because of a difference in color.[4]

(2) Some patients eventually accept differences in color, but only after considerable anxiety and confusion caused by the change.

(3) Patients taking multiple medications often identify specific drugs by capsule color and follow their physicians' dispensing instructions by relying upon color. Changes in color

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4. As the District Court found:

> "The court finds the colors are functional in several respects. First, many elderly patients associate the appearance of their medication with its therapeutic effect. There was testimony that some patients refuse to take equivalent drugs of a different color despite explanation of the equivalence by their doctors. Other patients eventually accept equivalent drugs of a different appearance if their physician assures them that the prescription was filled correctly, but are caused considerable anxiety and confusion by the change. When patients associate the drug with its therapeutic effect in this manner, to insist that defendants use a different color would unjustifiably put them at a competitive disadvantage. *Thus color is an important ingredient in the commercial success of the product.*" *Id.* (63a). (Emphasis added.)

among different brands for the same product are thus a certain source of confusion, particularly for the elderly patient.

(4) Capsule color serves to distinguish multiple dosage strengths of the same ingredient.

(5) Uniform capsule color is an aid in drug identification in emergency situations. *See id.*

Because of the foregoing, some outlets for the dispensing of prescription drugs, particularly hospitals, refuse to purchase equivalent generic products in different colors because of the confusion and anxiety it may cause for patients.[5]

After the appearance of petitioners' generic cyclandelate in the market, New York State, in 1977, enacted what is commonly known as a "drug substitution law". *See* N.Y. Educ. Law, §§6810, 6816, 6816-a (McKinney's Supp. 1981) (121a). This statute and its implications for competition in the pharmaceutical industry provide a critical setting for the issues raised in this case. Under the new statute, the sale of lower-priced generic equivalents is encouraged as a matter of public policy by altering the traditional practice under which a pharmacist is required to dispense a particular brand name if that name is specified on a prescription.

Recognizing that many physicians know drugs only by their brand name and not by the generic name, the statute directs that

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5. "The functional aspect of the color of the capsules is further evidenced by the fact that the parent of Inwood discontinued sale of cyclandelate in a green color because the different color was not accepted by hospitals, pharmacies and wholesalers in the light of the potential for confusion. One hospital official testified that he refused to purchase cyclandelate in a green capsule." *Id.* at 399 (63a-64a).

pharmacists may (and in most cases must) supply a lower-cost generic product, even if a brand-name is specified. This is so unless the doctor indicates on a special line of the prescription form that only the brand-name product is to be dispensed. *See generally, Pharmaceutical Society of State of New York v. Lefkowitz*, 586 F. 2d 953 (2d Cir. 1978). The purpose of New York's generic substitution law undeniably reflects a commitment to generic prescribing and encouraging the use of low-cost generics by the consuming public. *Id.* at 957.

Petitioners' cyclandelate products are equivalent to Ives' Cyclospasmol product. Under the law of New York State, petitioners' cyclandelate may be substituted for respondent's product if the physician has not barred such substitution on the prescription form. *See* N.Y. Educ. Law, §6810(6) (McKinney's Supp. 1981) (114a). As this Court has pointed out, it is very well known that drug prices vary widely, *see Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 763-764 (1976); and generic companies afford the consumer significant savings in the cost of drug products. Petitioners do in fact offer their cyclandelate products to customers at a "substantially lower price" than that charged for the Ives "Cyclospasmol" brand. *Ives IV* at 541 (76a).

Since forty-eight states, the District of Columbia and Puerto Rico have adopted a generic substitution law,[6] the prospect of patient resistance to color changes is now of even greater significance than ever before. If brand-name companies are granted a monopoly on the color of their pharmaceutical products, patient resistance to color changes, while perhaps aiding brand-name companies, will serve to impede and perhaps

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6. *See Competition in the Drug Industry: Hearings Before the Subcomm. on Oversight & Investigations of the House Comm. on Energy and Commerce*, 13, 91 Cong., 1st Sess. (March 10, 1981).

frustrate the economic savings sought to be encouraged by the drug substitution legislation. The District Court expressly so found. *See Ives III*, 488 F. Supp. at 401-02 (69a).

On the eve of the effective date of the landmark New York drug substitution law, Ives commenced the instant case. Ives sought to prohibit petitioners from continuing their then almost two-year-old practice of utilizing the familiar blue and blue/red colors for their cyclandelate capsules. *See Ives I* at 943 (5a). Ives' complaint asserted, *inter alia*, that petitioners' marketing of these capsule colors was actionable under both federal and state law as "unfair competition". Jurisdiction of the District Court was based on 28 U.S.C. §§1331(a), 1338(a) and (b). *See Ives I* at 942 (5a).

Ives first sought a preliminary injunction on the grounds that petitioners' use of the identical capsule colors constituted a false description or designation of origin within the meaning of §43(a) of the Lanham Act, 15 U.S.C. §1125(a), and that it violated the New York State law of unfair competition. Ives further claimed that petitioners were liable for "contributory trademark infringement". Except in a minor respect not at issue herein, the District Court denied the motion for preliminary injunction. *See Ives I* (27a).

On appeal, the Second Circuit affirmed the denial of the preliminary injunction. Judge Friendly found that, in view of the evidence of functionality of color produced below and Ives' failure to demonstrate any secondary meaning for its capsule colors, Ives had not sufficiently made out a case for unfair competition under either state or federal law to support the entry of an injunction. *See Ives II* (28a).

On the question of contributory trademark infringement, Ives' proof was limited to only 15 instances of improper

substitution of cyclandelate for Cyclospasmol.[7] Accordingly, the Second Circuit found that these 15 instances, which were restricted to pharmacists who had a "proclivity toward illegal substitution," *see Ives I* at 950 (24a), were not sufficient to render petitioners contributorily liable for the alleged trademark infringement which had occurred.[8] The court also noted that "discovery and trial might show that the practice was much more widespread, or, on the other hand, as defendants suggest, that the pharmacies in question were known bad actors and few others engaged in such practices." *Ives II* at 644 (53a).

For the subsequent trial, Ives conducted an extensive

7. Improper substitution is akin to the tort of "passing off". In the context of prescription pharmaceuticals under New York State law, it occurs when a doctor prescribes the brand-name product and signs the prescription form "dispense as written". Thereafter, when the patient presents the prescription to the druggist, the druggist commits improper substitution and a criminal offense if he or she fills the prescription with a product which is not the product specifically requested by the physician. Trademark infringement may occur if the druggist affixes a company's trademark name to the label of the container which does not contain the trademarked product. *See generally*, N.Y. Educ. Law, §§6810, 6815(2)(h), (j); 6816, 6816-a (McKinney's Supp. 1981); and N.Y. Pub. Health Law, §206(1)(o) (McKinney's Supp. 1981) (112a-122a). The Cyclospasmol name appeared on the product in 12 out of 15 instances noted above.

8. Traditionally, the judicial doctrine of contributory trademark infringement, which has been read into §32 of the Lanham Act, requires a wilful participation or assent, even if only by implication, in another party's acts of trademark infringement. *See Ives II* at 636 (35a); *Coca-Cola Co. v. Snow Crest Beverages*, 64 F. Supp. 980, 999 (D. Mass. 1946), *aff'd*, 162 F. 2d 280 (1st Cir.), *cert. denied*, 332 U.S. 809 (1947). Since petitioners were not shown to have any knowledge of these 15 "bad actors", the Second Circuit agreed that petitioners could not be liable as contributory infringers on this evidence. Additionally, the Court of Appeals pointed out that:

> "the judge was right in concluding that the protection conferred by . . . section [32] is *narrower* than that afforded by §43(a) . . ." *Id.* (34a) (emphasis added).

nationwide survey involving 12,000 physicians attempting to establish that its capsule colors had a secondary meaning,[9] as required by §43(a) of the Lanham Act. Additionally (and ultimately of critical importance), Ives conducted a survey of 83 pharmacists, limited to New York State, to evaluate the process by which cyclandelate products were being lawfully substituted under the New York State drug substitution law.

The latter survey found that in a total of 10 instances the pharmacist who was authorized to substitute a generic cyclandelate product had done so, but had not fully complied with the labeling requirements of the law. *See N.Y. Educ. Law*, §6816 (McKinney's Supp. 1981) (112a). Nine of the ten druggists orally advised the patient that they were dispensing the generic drug. Five of the ten also wrote on the product label the word "generic", or its abbreviation, before or after the name "Cyclospasmol". In only one instance was the product labeled "Cyclospasmol" without any written or oral indication of generic status. Most significantly, the evidence showed only one instance out of the 83 test shoppings where a patient was charged the brand-name price for a generic product. *See Ives III* at 397-398 (60a).

In a comprehensive opinion, the District Court, after a bench trial, denied all of Ives' claims for relief against petitioners. The court found that to give Ives a monopoly of capsule colors would severely inhibit the purposes of the New York drug substitution law, because the colors served very significant functional purposes. *Ives III* at 401-402 (69a). *See also, Ives II* at 644 (52a). The court further found that Ives had not established that it was entitled to a monopoly over the colors blue and blue/red since the colors had not achieved any secondary meaning. In addition, it held that petitioners were not

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9. This attempt was unsuccessful, as discussed *infra*.

liable for contributory trademark infringement under §32 of the Lanham Act since they did not continue to sell their generic drugs to pharmacists whom they knew, or had reason to know, were engaging in trademark infringement of Ives' Cyclospasmol mark. *Ives III* at 397 (59a).

Upon the second appeal, however, the Second Circuit reversed in a split opinion, reaching only the question of contributory trademark infringement, without addressing the other issues in the case relating to §43(a) of the Lanham Act and the state law of unfair competition.[10]

The majority opinion in *Ives IV* acknowledged that there was no additional evidence of improper substitution produced by Ives, and that the original evidence of improper substitution was not sufficient to establish contributory trademark infringement. Rather, the majority focused upon Ives' additional evidence which showed instances wherein a druggist, who was authorized to substitute the generic drug (cyclandelate), affixed the word "Cyclospasmol" on the label of the dispensing container for such capsules, together with either the word or symbol indicating that it was a generic product, or an oral explanation that the generic product was being dispensed. The Second Circuit held that pharmacists who labeled the products dispensed as "generic Cyclospasmol" were guilty of trademark infringement. Petitioners were found to be contributorily liable for such infringement because petitioners had used catalogs and

10. Despite the District Court's extensive finding discussed earlier as to functionality of color, the Court of Appeals declared only that these legitimate reasons for using lookalike capsules were "unconvincing", *Ives IV* at 544 (85a). As Judge Mulligan (the only judge who sat on both Court of Appeals panels) noted in his dissenting opinion, the "majority does not characterize this finding or other evidence of functionality discussed in the opinion below as 'clearly erroneous' . . . Judge Nickerson's findings of fact based upon the testimony of witnesses who appeared before him cannot be disregarded by this court." *Id.* at 547 (91a) (footnote omitted).

price sheets to advertise their products to drug wholesalers and hospital purchasing agents. The catalogs and price sheets provided comparisons of the wholesale price for the brand-name, in contrast to that of the generic product, and in some instances had identified their respective color configuration.[11] The Court of Appeals held that these ten instances were sufficient to establish liability for contributory trademark infringement, even though petitioners Inwood and Premo herein were not shown to have distributed any of their price sheets or catalogs to the pharmacists who allegedly committed the trademark infringement.[12]

The ruling of the Second Circuit holds for the first time that describing a drug product as a generic version of a trademarked item constitutes trademark infringement. Petitioners were held liable for such a description by pharmacists, to whom they do not even sell directly, under the further theory that, in view of petitioners' comparative advertising to their wholesale accounts, petitioners should have known that pharmacists who bought from the wholesalers "might" label their products as a generic version of the trademarked item. While the reasoning involved in reaching this conclusion is unclear,[13] the majority found that

11. In contrast to petitioners' marketing practices, Ives spent more than $10,000,000 in promotional and advertising expenses in detailing its products by having salesmen make personal visits to physicians, distributing samples and promotional materials. *See Ives III* at 396 (57a).

12. It is clear from the *Ives IV* opinion that these instances were considered trademark infringement on the part of pharmacists and that this was the evidence which was critical to the Court of Appeals' finding that petitioners were liable for contributory trademark infringement. *See Ives IV* at 542-543 (82a) ["The additional evidence introduced by Ives at trial was *clearly sufficient* to establish a §32 violation." (emphasis added).]

13. As one legal commentator recently observed:

> "Perhaps one's expectations must necessarily be limited, but the level of analysis in the recent colour get-up judgments

(Cont'd)

the brand-name company must be granted the perpetual, exclusive right to use the capsule colors in question.[14]

(Cont'd)

has fallen extra-ordinarily low. The courts seem to be indulging in non-sequiturs, fits of pique, and bizarre overreactions, instead of making measured, rational, dispassionate responses to whatever problems there are in resolving these business conflicts. *Moreover, the distribution of what seems to be error and mistake is now quite unrandom; there has been a definite tilt in favour of the brand name drug companies, against the generic sellers.* One would not think this to be one of the great political issues of the times; that distorts perception and judicial impartiality. Yet the courts seem to be reacting to generic sellers as if they were trying to subvert Government. Why the courts are doing so seems inexplicable in terms of ordinary common law legal analysis methods based on the categories of trade mark and unfair competition law as they have been developed in regard to other products. Something may be going on in these cases that is not reflected in the lines of the courts' published opinions. To predict these judgments is now simple, for the same side always wins. To understand the judgments, perhaps, use of a different discipline is required." *See* R.H. Stern, *The Persantine, Librax & Elavil Decisions: Colourful Brands of Drugs*, 2 Eur. Intel. Prop. Rev. 59 (1981). *See also*, 3 R. Callman, *Unfair Competition* §82.1(m) at 171-180 (Cumm. Supp. 1979).

14. The decision of the Second Circuit:

". . . [requires the] grant [of] a permanent injunction giving plaintiff a monopoly over the colors blue and a combination of blue and red for capsules of the same shape and size as those used by plaintiff to sell Cyclospasmol." *See Ives V* at 2 (98a).

REASONS FOR GRANTING THE WRIT

I.

Certiorari should be granted to determine whether the Second Circuit properly held that truthful comparative use of another's trademark in labeling and advertising gives rise to liability for trademark infringement.

The Second Circuit, by its ruling, has effected a radical change in the law of trademarks which threatens the entire concept of comparative trademark advertising. Petitioners were held contributorily liable for the acts of a pharmacist in labeling of cyclandelate products. The critical element in finding this contributory trademark infringement liability was the "additional evidence" by which Ives showed that some pharmacists, while lawfully substituting a generic product under the New York drug substitution law, had labeled or described the product as "generic Cyclospasmol," either orally or in writing. Never before has any court held that the mere description of one product as a generic equivalent of a trademarked product constitutes trademark infringement under the Lanham Act.

To state, as occured here, that a product is "generic Cyclospasmol" clearly indicates that it is not the trademarked product, but rather, a generic version thereof. Yet without any explanation, the Second Circuit has held that such acts constituted trademark infringement by the pharmacist.[15]

Similarly, in finding petitioners contributorily liable for this supposed trademark infringement, the court held that liability

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15. If these acts had not constituted trademark infringement, petitioners would, of course, not have been found liable for contributory trademark infringement.

was triggered by petitioners' exercise of their commercial free speech rights. Such speech took the form of brochures and price lists which utilized comparative advertising. The price paid by petitioners for the exercise of this right to advertise was the finding of liability for contributory trademark infringement, and an injunction against the use of a critical, competitive product feature — the blue and blue/red colors.

Justice Holmes, speaking for this Court in 1910, established the basic principle that a competitive product may be labeled with specific reference to the trademark of another product without invoking liability for trademark infringement:

> "The real intent of the plaintiff's bill, it seems to us, is to extend the monopoly of such trademark or trade name as she may have to a monopoly of her type of bitter water, by preventing manufacturers from telling the public in a way that will be understood what they are copying and trying to sell. But the plaintiff has no patent for the water, and the defendants have a right to reproduce it as nearly as they can. They have a right to tell the public what they are doing and to get whatever share they can in the popularity of the water by advertising that they are trying to make the same article and think that they succeed. . . . By doing so they are not trying to get the good will of the name, but the good will of the goods." *Saxlehner v. Wagner*, 216 U.S. 375, 380 (1910).

In the instant case, the notation of the term "generic" on the capsule container, or the pharmacist's orally informing the patients that they were receiving the generic product (although

labeled as "Cyclospasmol"),[16] excluded the notion that the pharmacist was selling Ives' goods. Thus, the critical facts supporting application of the rationale of contributory infringement were lacking in the instant case. With respect to the "additional evidence" adduced by Ives, patients knew that they were not getting the "trademarked" goods, and they were not charged the higher price usually applicable for the "trademarked" item. Based on the clear precedent prior to *Ives IV*, this use of the written and oral term "generic Cyclospasmol" or "same as Cyclospasmol" or "equivalent to Cyclospasmol" was not an infringement of the Cyclospasmol trademark. *See Champion Spark Plug Co. v. Sanders*, 331 U.S. 125, 129-130 (1947); *Prestonettes, Inc. v. Coty*, 264 U.S. 359, 368-369 (1924); *Societe Comptoir de L'Indus., etc. v. Alexander's Dep't Stores*, 299 F. 2d 33 (2d Cir. 1962); *Taylor Instrument Companies v. Fawley-Brost Co.*, 139 F. 2d 98, 101 (7th Cir. 1943), *cert. denied*, 321 U.S. 785 (1944); *Electric Auto-Lite Co. v. P&D Mfg. Co.*, 78 F. 2d 700 (2d Cir. 1935), *cert. denied*, 296 U.S. 648 (1936); *Geisel v. Poynter Products*, 295 F. Supp. 331 (S.D.N.Y. 1968). *Accord, Smith v. Chanel, Inc.*, 402 F. 2d 562 (9th Cir. 1968); *Viavi Co. v. Vimedia Co.*, 245 F. 289 (8th Cir. 1917), *cert. denied*, 246 U.S. 664 (1918).

The legal commentators have distilled the concepts expressed in these cases into what, until the *Ives IV* decision, was a basic and universally recognized tenet of trademark law:

> "[t]he law is that it is neither trademark infringement nor unfair competition to truthfully compare competing products in advertising, and in doing so, to identify by trademark, the competitor's goods. . . . An analogous situation

16. Oral explanations are clearly sufficient and in fact have sometimes been required to avoid liability for trademark infringement. *See, e.g., Coca-Cola Co. v. Dorris*, 311 F. Supp. 287, 292 (E.D. Ark. 1970).

> is that in which a seller has attempted to copy a public domain feature of a competitor's product. Is the legal copier free to tell the buyer of the close identity between the products? *If a seller has the right to copy public domain features of his competitor's goods, then, as a corollary, he must have the right to inform the public of this fact.* If legal imitation is the 'life-blood of competition,' *then the imitator who sells a cheaper version of the original is entitled to so inform the public.*" J.T. McCarthy, *Trademarks and Unfair Competition,* §25.14 at 192 (1973) (emphasis added).

The appellate court's disregard of this basic right to competitive, comparative use of a trademark name takes on even more ominous ramifications when the asserted rationale for the finding of *contributory* trademark infringement is considered. Petitioners Inwood and Premo, who do not, for the most part, sell or advertise directly to retail pharmacists were held contributorily liable for the supposed retail pharmacist infringement, at least in significant part, because petitioners had engaged in comparative advertising to their wholesaler accounts.[17]

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17. The court observed:

> "Ives contends that appellees violated §32 of the Lanham Act because of their deliberate use of lookalike capsules *and pro-substitution catalogues* encouraged retail druggists to substitute generic cyclandelate illegally for CYCLOSPASMOL." *Ives IV* at 541 (76a) (emphasis added).
>
> "By using capsules of identical color, size, and shape *together with a catalog describing their appearance and*

(Cont'd)

The Second Circuit holding has placed any company who comparatively advertises on the horns of a dilemma. If it chooses to engage in comparative advertising, it runs the risk that, under the Second Circuit opinion, it may be automatically liable for contributory trademark infringement and thereby lose the right to *market an important functional and competitive feature of* its *product.* If it chooses not to comparatively advertise under this threat of liability, then as against it the competitor's trademark (as Justice Holmes observed) has been impermissibly extended to the product itself. *See Saxlehner v. Wagner,* 216 U.S. at 380.

In addition to being at odds with the clear spirit of the principle ". . . that use of another's trademark to identify the trademark owner's product in comparative advertising is not prohibited by either statutory or common law . . . ,"[18] the *Ives IV* decision conflicts with the current holdings of this Court concerning the right to commercial free speech. *See e.g., Bates v. State Bar of Arizona,* 433 U.S. 350 (1977).

The Second Circuit has taken petitioners' legitimate exercise of their First Amendment right to comparatively advertise and found that such exercise is punishable by becoming subject to an injunction on the use of a competitive color, under the judicial doctrine of contributory trademark infringement. The First

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(Cont'd)

> *listing comparative prices of CYCLOSPASMOL and generic cylandelate,* appellees could reasonably anticipate that their generic drug product would by a substantial number of druggists, be substituted illegally for Ives' trademarked CYCLOSPASMOL or that bottles of their lower-priced product might be mislabeled as CYCLOSPASMOL, all to the druggists' economic advantage." *Id.* at 543 (83a) (emphasis added).

18. *Smith v. Chanel, Inc.,* 402 F. 2d at 565.

Amendment right to free speech cannot be so cavalierly stifled and chilled. The Second Circuit failed to engage in any type of balancing test in order to ascertain whether such liability was constitutionally permissible or necessary.

As this Court noted in *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. at 763-764, in striking down a prohibition of prescription drug advertising:

> "When drug prices vary as strikingly as they do, information as to who is charging what becomes more than a convenience. It could mean the alleviation of physical pain or the enjoyment of basic necessities."

In recognition of this Court's affirmation of the right to commercial free speech, other courts have recognized that the Lanham Act should not be construed in a manner that would bring it into conflict with First Amendment interests. *Stop the Olympic Prison v. U.S. Olympic Committee*, 489 F. Supp. 1112, 1124 (S.D.N.Y. 1980). *See also, Triangle Publications, Inc. v. Knight-Ridder Newspapers, Inc.*, 445 F. Supp. 875, 884 (S.D. Fla. 1978), *aff'd on other grounds*, 626 F. 2d 1171 (5th Cir. 1980) (court observed that comparative advertising which uses another's trade name "is in harmony with the fundamental objectives of free speech and free enterprise in a free society."); *Fur Information and Fashion Council v. E.F. Timme & Son, Inc.*, 364 F. Supp. 16, 22 (S.D.N.Y. 1973), *aff'd on other grounds*, 501 F. 2d 1048 (2d Cir.), *cert. denied*, 419 U.S. 1022 (1974).

Here the Second Circuit has penalized both the label statement of generic equivalence and the advertisement of comparative availability without considering the limitations which the First Amendment places on judicial interference

with the process of communicating essential competitive information. It is respectfully submitted that, in view of the far-reaching consequences of *Ives IV*, so drastic an alteration in traditional concepts of trademark law, which alteration also impinges on basic First Amendment rights, should not be permitted to take effect without the benefit of full scrutiny by this Court by way of certiorari, as requested herein.

II.

Certiorari should be granted to determine whether the Second Circuit properly held that Section 32 of the Lanham Act (15 U.S.C. §1114) grants a trademark owner monopoly rights in the color of its product.

The ruling by the Court of Appeals automatically vests in the owner of every trademark an accompanying anti-competitive right in the color or trade dress of its product. Under the Second Circuit's reasoning, every time a competitor imitates color or trade dress, he might "reasonably anticipate" that someone in the chain of distribution might either intentionally or accidentally misapply the wrong trademark to the goods in question. Since this will always be true, every trademark would necessarily carry with it an absolute right to the trade dress or color in question.

In so ruling, the Court of Appeals has radically altered existing law as to the protection which can be afforded to trade dress or color. Heretofore, if trade dress or color included functional features, no monopoly rights could be obtained outside the patent laws. Yet in the face of comprehensive findings of functionality by the District Court, the Court of Appeals grants monopoly rights under the rubric of supposed liability for contributory trademark infringement.

Previously, the issue of whether or not the color of prescription pharmaceuticals could be copied by a subsequent manufacturer has been determined under the law of trade dress, under §43(a) of the Lanham Act, 15 U.S.C. §1125(a), or the applicable state law of unfair competition. Courts have denied proprietary rights to color unless the color was shown to be non-functional. *See e.g., William R. Warner & Co. v. Eli Lilly & Co.*, 265 U.S. 526 (1924). *But cf., SK&F v. Premo Pharmaceutical Laboratories, Inc.*, 625 F. 2d 1055 (3d Cir. 1980). In addition, the courts have required a distinct showing of secondary meaning before proprietary rights could be obtained. *See, e.g., Upjohn Co. v. Schwartz*, 246 F. 2d 254 (2d Cir. 1957).

In this action, all of the traditional factors were determined in favor of petitioners' right to use the colors in question. The District Court found that the colors were functional, and that in any event no secondary meaning had been established. It thus rejected Ives' claim of an exclusive right to the specific color configurations. The Court of Appeals, however, in a departure from all prior precedent in this area of law, found that a company may have certain types of proprietary color rights by virtue of the trademark laws of the United States.

The above *Ives IV* determination is contrary to two well-established principles. First, color itself, which is not impressed upon an arbitrary design, nor employed in association with characteristics which would serve to distinguish the article as made and sold by a particular company, does not constitute a valid trademark, and is not entitled to protectible status, absent other evidence of unfair competition. *A. Leschen & Sons Rope Co. v. Broderick & Bascom Rope Co.*, 201 U.S. 166 (1906). *See also, Coats v. Merrick Thread Co.*, 149 U.S. 562 (1893).

The plain blue and blue/red colors of respondents' drug capsules are not part of an arbitrary design, nor did they

indicate any "secondary meaning". Therefore, the decision of the Court of Appeals flies in the face of a long series of historical decisions which explicitly state that color can be neither trademarked nor monopolized. *See Norwich Pharmacal Co. v. Sterling Drug Inc.*, 271 F. 2d 569 (2d Cir. 1959), *cert. denied*, 362 U.S. 919 (1960); *Tas-T-Nut Co. v. Variety Nut & Date Co.*, 245 F. 2d 3 (6th Cir. 1957); *Campbell Soup Co. v. Armour & Co.*, 175 F. 2d 795 (3d Cir.), *cert. denied*, 338 U.S. 847 (1949); *Newcomer & Lewis v. Scriven Co.*, 168 F. 621, 623 (6th Cir. 1909); *Diamond Match Co. v. Saginaw Match Co.*, 142 F. 727 (6th Cir. 1906). *See also, Dallas Cowboys Cheerleaders, Inc. v. Pussycat Cinema, Ltd.*, 604 F. 2d 200, 204, n.6 (2d Cir. 1979); *Plastilite Corp. v. Kassnar Imports*, 508 F. 2d 824 (C.C.P.A. 1975); *In re Shaw*, 184 U.S.P.Q. 253 (T.T.A.B. 1974); *American Basketball Assoc. v. A.M.F. Voit, Inc.*, 358 F. Supp. 981 (S.D.N.Y.), *aff'd without opinion*, 487 F. 2d 1393 (2d Cir. 1973), *cert. denied*, 416 U.S. 986 (1974).

Second, the decision of the Court of Appeals runs afoul of this Court's classic determination that freedom to copy the unpatented wares of a competitor is critical to a competitive economy.

In *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225 (1964), and in *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234 (1964), this Court ruled that once an article is no longer entitled to protection under the federal patent laws, or is not covered by a federal trademark, the public is entitled to share in its goodwill, and thus it may be copied exactly.

> "To forbid copying would interfere with the federal policy, found in Art. I, §8, cl.8 of the Constitution and in the implementing federal statutes, of allowing free access to copy whatever the federal patent and copyright laws leave in the public domain." *Id.*

To hold otherwise, the Court ruled, would be to extend the patent monopoly beyond that contained in the patent. *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. at 230. As this Court noted in *Compco:*

> "That an article copied from an unpatented article could be made in some other way, that the design is 'non-functional' and not essential to the use of either article, that the configuration of the article copied may have a 'secondary meaning' which identifies the maker to the trade, or that there may be 'confusion' among purchasers as to which article is which or as to who is the maker, may be relevant evidence in applying a State's law requiring such precautions as labeling; however, and regardless of the copier's motives, *neither these facts nor any others can furnish a basis for imposing liability for or prohibiting the actual acts of copying and selling.*" 376 U.S. at 238 (emphasis added).

See also, American Safety Table Co. v. Schreiber, 269 F. 2d 255, 272 (2d Cir. 1959).

As a corollary to this principle, this Court has established that, even in the face of a finding of trademark infringement, the relief as ordered by the Court of Appeals in this case is impermissible. Rather, prophylactic requirements, such as labeling, that eliminate or minimize any confusion as to source that may result from imitation protect the originator's interest in identification of source, while permitting competitors to market its product "in the form in which the public has become accustomed to see the article." *See Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111, 120 (1938).

This limitation was first set forth in this Court's decision in *William R. Warner & Co. v. Eli Lilly Co., supra,* which enunciated the proper limitations on the scope of relief that should have been applied to the instant case:

> "Nevertheless, the right to which respondent is entitled is that of being protected against unfair competition, not of having the aid of a decree to create or support, or assist in creating or supporting, monopoly of the sale of a preparation which everyone, including petitioner, is free to make and vend. The legal wrong does not consist in the mere use of chocolate as an ingredient, but in the unfair and fraudulent advantage which is taken of such use to pass off the product as that of respondent. *The use dis-associated from the fraud is entirely lawful, and it is against the fraud that the injunction lies.* But respondent being entitled to relief, is entitled to effective relief; . . . Clearly, the relief should extend far enough to enjoin petitioner, and its various agents, from, directly or indirectly, representing or suggesting to its customers the feasibility or possibility of passing off Quin-Coco for Coco-Quinine. *The Court of Appeals held that petitioner should be unconditionally enjoined from the use of chocolate. We think this goes too far.* [As] an effective remedy, we think the decree fairly may require that the original packages sold to druggists shall not only bear labels clearly distinguishing petitioner's bottled product from the bottled product of respondent, but that these labels shall state affirmatively that the preparation is not to be sold or dispensed as Coco-Quinine or be used in filling prescriptions

> or orders calling for the latter." *William R. Warner & Co. v. Eli Lilly Co.*, 265 U.S. at 532-533.

See also, Coca-Cola Co. v. The Koke Company of America, 254 U.S. 143 (1920) (court refused to allow injunction prohibiting use of cola coloring in trademark infringement action).[19]

The holding of the Second Circuit, which prohibits color copying, "*goes too far.*"[20] As this Court determined in *Lilly*, the use of plaintiff's colors by defendant *disassociated* from the fraud of passing off or mislabeling is *lawful*, and it is against the fraud which the injunction must issue. *Accord, Upjohn Co. v. Schwartz, supra;* and *Smith, Kline & French Laboratories v. Clark & Clark*, 157 F. 2d 725, 730-731 (3d Cir.), *cert. denied*, 329 U.S. 796 (1946).

This critical distinction was ignored by the Court of Appeals. Rather, Judge Mansfield stated that a prohibition upon the copying of the unpatentable, untrademarkable colors of Cyclospasmol was necessary, since:

> "*it would . . . give Ives the protection to which it is entitled to for its trademarked product.*" *Ives IV* at 545 (86a) (emphasis added).

Petitioners respectfully submit that this statement is contrary to the law of trademarks, as it has been interpreted by

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19. In *Coca-Cola*, Justice Holmes noted that "the product[,] including the coloring matter[,] is free to all who can make it if no extrinsic deceiving element is present." *Id.* at 147.

20. The court justified it only on the grounds that an injunction was the "simplest" way to protect respondent. *Ives IV* at 545 (86a).

this Court since the turn of the century. The rights granted by the trademark laws to protect a name do not include the coloration of the trademarked product.

Ives IV accomplishes the opposite result by applying a *per se* rule in order to find liability for contributory trademark infringement. Under the Second Circuit's standard, the mere sale of a similar-looking product is enough to satisfy the intent requirement inherent in a finding of contributory trademark infringement.[21] Even more crucial is the fact that there was no evidence that look-alike capsules actually encouraged or assisted or facilitated the alleged mislabeling.

As a result of the new rule of law established by the Second Circuit, the owner of the trademark can now fully monopolize its trade dress. Such a decision runs counter to Congress' intent in adopting §32 and to this Court's analysis of the law of permissible copying Trademarks can now be used as patent substitutes or to further perpetuate product monopolies. The Second Circuit decision has turned the law of trademarks on its head: because of the functional nature of color, fully effective competition will be severely limited in the manufacture and sale of generic drugs. *Cf. International Order of Job's Daughters v. Lindeburg & Co.*, 633 F. 2d 912, 917-920 (9th Cir. 1980), *cert. denied*, 49 U.S.L.W. 3931 (June 15, 1981).

If the opinion of the Second Circuit is not overturned,

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21. It should be emphasized that, as Judge Mulligan pointed out in his dissent, "there is not a scintilla of evidence to suggest that the defendants sold to those pharmacies knowing or having reason to believe that illegal substitution or mislabelling had occurred." *Ives IV* at 546 (87a). The latest rule in the Second Circuit thus is also inconsistent with the standards established by both Judge Friendly in *Ives II* and by Judge Wyzanski in his leading opinion of *Coca-Cola Co. v. Snow Crest Beverages, supra.*

brand-name companies will be able to utilize §32 to extend incidents of their patent monopolies by automatically prohibiting generic companies from marketing their products in the appearance to which the public has grown accustomed. We respectfully urge this Court to recognize that the monopolization of color rights sanctioned by the Second Circuit portends a serious threat to effective competition in trademarked items, in general, and pharmaceutical products, in particular. Certiorari is urgently needed to resolve these issues of vital importance to the public.

CONCLUSION

It is respectfully requested that a writ of certiorari issue to review the judgment of the United States Court of Appeals.

Respectfully submitted,

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APPENDIX A — OPINION OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK, *IVES LABORATORIES, INC. v. DARBY DRUG CO., INC.*, 455 F. SUPP. 939 (E.D.N.Y. 1978)

United States District Court
E. D. New York
No. 78 C 372

Aug. 2, 1978.

IVES LABORATORIES, INC.,

Plaintiff,

v.

DARBY DRUG CO., INC., Inwood Laboratories Incorporated, Lowitt Laboratories, Inc., MD Pharmaceutical Company, Inc., Premo Laboratories, Inc., Rugby Laboratories, Inc., and Sherry Pharmaceutical Co., Inc.,

Defendants.

Egon E. Berg, New York City, and Rogers, Hoge & Hills, New York City, for plaintiff; Vito V. Bellino, Mortimer Altin, Steven J. Baron, William F. Weigel, Marie Driscoll, Charles J. Raubicheck, of counsel.

Salon, Bloustein & Raybin, New York City (Robert V. Marrow, New York City, of counsel), for defendants Darby, Rugby, Sherry, & MD.

Kirschstein, Kirschstein, Ottinger & Cobrin, P.C., New York City (Peter T. Cobrin, New York City, of counsel), for defendant Premo Pharmaceutical.

Appendix A

Bass Ullman & Lustigman, New York City (Sheldon S. Lustigman, New York City, of counsel) for defendant Inwood Laboratories.

OPINION

NICKERSON, District Judge.

Plaintiff Ives Laboratories, Inc. ("Ives"), which manufactures and sells under the registered trademark "Cyclospasmol" a prescription drug of the generic name of "cyclandelate", brought this suit against defendants under the Trademark Act of 1946, as amended, (known as the "Lanham Act"), 15 U.S.C. §§1051ff., for trademark infringement and false designation of the origin of, and false description of, goods in commerce, and under New York common and statutory law for unfair competition. Plaintiff moves for an order preliminarily enjoining defendants from (1) using the trademark "Cyclospasmol" or any word confusingly similar including "Spasmol", (2) manufacturing and selling generic cyclandelate in capsules which are blue, red or a combination of blue and red, and (3) continuing other alleged acts of unfair competition.

I

Since 1958 plaintiff Ives, a New York corporation, and its predecessors and parent company American Home Products Corporation have sold cyclandelate under the registered trademark "Cyclospasmol". The drug is so-called peripheral vasodilator said to produce an increase in blood flow and is administered not to cure but to inhibit the progressive and debilitating conditions caused by certain vascular diseases, generally in the aged. Its use is therefore long term, for most patients a lifetime.

Appendix A

Before the expiry date on April 26, 1972 of a patent protecting cyclandelate plaintiff or its predecessors had the exclusive right to sell the drug in the United States. Commencing in 1962 plaintiff has market dosages of 200mg. in a pale blue capsule having an imprint reading "Ives 4124". Since 1975 plaintiff has sold 400mg. dosages in a red and blue capsule with the imprint "Ives 4148". Plaintiff has directed its extensive advertising and promotion of "Cyclospasmol" primarily to physicians. In addition, on personal visits to doctors plaintiff's representatives have distributed more than two million "starter" samples. Some one hundred and twenty five million of the 200mg. and 400mg. capsules have been sold since 1962. Over the past ten years such sales have exceeded $65,000,000.

Defendants are three drug manufacturers, three wholesalers, and one retail pharmacy. The three manufacturers, Premo Pharmaceutical Company, Inc. ("Premo"), Inwood Laboratories, Incorporated ("Inwood"), and MD Pharmaceutical Company, Inc. ("MD"), purchase cyclandelate powder and empty capsules and fill and sell them as generic cyclandelate to wholesalers, hospitals, retail pharmacies and others.

Premo and Inwood, both New York corporations, and MD, a California corporation, distribute 200mg. capsules of a pale blue color identical or very similar to that used by plaintiff. Premo and Inwood also distribute 400mg. capsules identical or very similar in colors to plaintiff's 400mg. capsules. Until recently none of the capsules distributed by the manufacturers bore any name or other identification. On June 26, 1978 Premo filed an affidavit stating that it in the future would imprint "Premo" on its capsules and had discontinued using unmarked capsules.

Appendix A

The three wholesalers, Darby Drug Co., Inc. ("Darby"), Rugby Laboratories, Inc. ("Rugby"), and Sherry Pharmaceutical Co., Inc. ("Sherry") all New York corporations, are now under common ownership and management. They purchase generic cyclandelate capsules and resell them to wholesalers, doctors, pharmacies and others.

The manufacturers and the wholesalers promote the generic product as "comparable" or "similar" or "equivalent" to "Cyclospasmol". In some catalogs they refer to the color of the capsules. For purposes of the motion it is conceded that the cyclandelate sold by defendants has the same bioavailability as "Cyclospasmol" and that the two are bioequivalent, meaning that the therapeutic ingredients in both have an equivalent effect.

Recently Sherry, which had offered the drug under the name "Spasmol", abandoned that name. The other defendants have not sold under a brand name.

Defendant Lowitt Labs Inc. ("Lowitt"), a New York corporation, is a retail pharmacy. The complaint alleges that on receiving a prescription for "Cyclospasmol" Lowitt substituted generic cyclandelate and labelled the prescription bottle "Cyclospasmol". On consent the court entered a decree enjoining Lowitt from substituting cyclandelate from another source as plaintiff's "Cyclospasmol" and from using that trademark or one so similar as to be likely to cause confusion. The claim against Lowitt is thus not at issue, and the remaining defendants will be called "the defendants".

Appendix A

II

Plaintiff makes various contentions under both federal and New York State law. Plaintiff's first claim is under Section 32 of the Lanham Act, 15 U.S.C. §1114(1)(a), which imposes liability for the use of a copy or colorable imitation of a registered mark in selling, distributing or advertising of goods where the use is likely to deceive or cause confusion or mistake. Plaintiff asserts two kinds of violation of this section: (1) that Sherry infringed the "Cyclospasmol" mark by using the name "Spasmol" and (2) that the defendants have been guilty of "contributory infringement" of the "Cyclospasmol" mark. The latter claim is based on the assertion that defendants have induced pharmacies such as Lowitt to label containers of generic cyclandelate as "Cyclospasmol".

Plaintiff further contends that defendants are violating Section 43(a) of the Lanham Act, 15 U.S.C. §1125(a), by adopting the colors used by plaintiff and by promoting their products as comparable or equivalent, thus making "a false designation of origin" and a "false description or representation" as to the goods.

Finally plaintiff claims that by duplicating the appearance of plaintiff's capsules thus "placing an instrument of fraud" into the hands of retail pharmacists, defendants are guilty of unfair competition under New York common and statutory law.

III

This court has jurisdiction of the Lanham Act claims under 28 U.S.C. §1338(a) and, since more than $10,000 is in controversy, under 28 U.S.C. §1331(a). Those claims are sufficiently substantial to give the court jurisdiction under 28

U.S.C. §1338(b) of the related unfair competition claims. As to MD the court also has jurisdiction under 28 U.S.C. §1332, there being diversity of citizenship. MD has made a motion, now returnable September 1, 1978, to dismiss for lack of personal jurisdiction.

IV

The criteria for issuance of a preliminary injunction have been stated by the Court of Appeals for the Second Circuit: a clear showing by plaintiff of possible irreparable injury and either (1) probable success on the merits or (2) sufficiently serious questions going to the merits to make them a fair ground for litigation and a balance of hardships tipping decidedly toward the plaintiff. *Selchow & Righter Company v. McGraw-Hill Book Company*, 580 F. 2d 25, at p. 27 (1978).

Defendants contend that, even if these criteria are met, a preliminary injunction should not issue because of the delay in bringing the action. Plaintiff, which by the summer of 1976 knew of the existence, but perhaps not the extent and manner, of some of the defendants' sales, did not file the motion until March 20, 1978.

Certainly as to Sherry's alleged infringement of "Cyclospasmol" by using "Spasmol" laches should not bar relief. Sherry has discontinued the name, and delay in seeking to prohibit its use has caused no harm. As to the other claims it is in the interest of the litigants and the public to decide the motion on grounds addressing the merits.

For the reasons stated in this opinion the court holds that, except for the claim of trademark infringement against Sherry, plaintiff has not made the showing prerequisite to issuance of a preliminary injunction.

V

Since Sherry has discontinued the use of the name "Spasmol" the claim that it infringes "Cyclospasmol" is now of diminished significance. Sherry suggests, but does not press the point, that "Cyclospasmol" is not a valid trademark because merely descriptive of the functions of the medication. But at least in the absence of a contrary showing the court may presume a registered trademark to be valid. 15 U.S.C. §1057(b). *Maternally Yours, Inc. v. Your Maternity Shop, Inc.*, 234 F. 2d 538, 542 (2d Cir. 1956).

Sherry also claims that the discontinuation of the name makes the matter moot. In 1977 Darby acquired Sherry and with it an inventory of cyclandelate which Sherry had been selling as "Spasmol". Assertedly that inventory has now been disposed of, orders have been and are being filled with cyclandelate sold under the Rugby name, and the name Spasmol has been deleted from the new Sherry catalog.

Even assuming what is stated, plaintiff is not bound to rely on Sherry's assurances. *Consumers Union of United States, Inc. v. Admiral Corporation*, 186 F. Supp. 800, 801 (S.D.N.Y. 1960); *Mercury Record Corp. v. Buckingham Record Co.*, 226 F. Supp. 427, 429 (S.D.N.Y. 1963). Plaintiff may therefore have a preliminary injunction against Sherry's use of "Spasmol".

VI

Consideration of plaintiff's claims based on contributory infringement of the "Cyclospasmol" trademark, false description or false designation of origin of goods under Section 43(a) of the Lanham Act, and unfair competition under the New York law

requires a tracing of the process which ends with the consumption of the product.

A patient may obtain cyclandelate only on a doctor's prescription, and New York law provides the manner in which such prescription must be made. Section 6810(6) of the Education Law requires the prescription form to state conspicuously: "This prescription will be filled generically unless physician signs a line stating 'dispense as written'." Two lines must appear on the form, one over the words "substitution permissible" and the other over the words "dispense as written."[1] The physician's signature on either validates the prescription.

Unless the physician otherwise directs, the pharmacist making a substitution must indicate on the label the name and strength of the drug and its manufacturer. Where a brand name drug is dispensed, Section 6815(2)(j) requires the pharmacist, unless the prescription otherwise explicitly states, to affix the brand name and the strength of the drug.

Any pharmacist who mislabels or makes an improper substitution is by Section 6816(1) guilty of a misdemeanor and by Section 6809 subject to civil monetary penalties. In addition his license may be revoked under Section 6808.

Plaintiff sells in packages identifying itself and displaying the trademark "Cyclospasmol". When he dispenses the product

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1. Section 6816-a(1) goes further and provides that a pharmacist "shall substitute a less expensive drug" having the same active ingredients if the physician signs above the words "substitution permissible" and the drug is on a list established under the New York Health Law. Plaintiff claims that cyclandelate is not on the list, and that druggists are thus not "required" to substitute. However, they may substitute if the physician has signed on the appropriate line.

the pharmacist removes the capsules from plaintiff's packages and places them in containers bearing his own label. If he follows the law, the phramacist then includes on the label, for example, "Cyclospasmol 200mg." "Ives" need not be mentioned on the label. Defendants' cyclandelate follows a similar course. Here the pharmacist must include on the label, for example, "Cyclandelate 200mg. Premo".

Plaintiff contends that defendants, by copying the colors in which "Cyclospasmol" is sold, by not imprinting (until recently in the case of Premo) their names on the capsules, and by advising pharmacists and others that the product is the generic equivalent of "Cyclospasmol", are placing and "instrument of fraud" in the hands of pharmacists, thereby unfairly appropriating business that would otherwise go to plaintiff. Plaintiff suggests not that physicians, hospitals or pharmacists are in doubt as to the identity or source of the product but rather that dishonest pharmacists, tempted no doubt by the generally lower price of the generic drug, will, quite contrary to the explicit directions of the doctors, fill prescriptions with defendants' capsules rather than those of plaintiff. The patient, says plaintiff, seeing the customary colors (and not noticing the absence of the "Ives" imprint or supposing plaintiff to have abandoned it) will assume he is getting what the doctor ordered.

Plaintiff insists that this is no mere hypothetical scenario and points to evidence that a number of pharmacies around the country have improperly filled prescriptions for "Cyclospasmol" with generic cyclandelate. Some, like Lowitt, have gone further and have falsely labeled the containers as containing "Cyclospasmol".

According to plaintiff the only effective manner in which to halt the pharmacists' practices is to reserve exclusively to

plaintiff the blue and red colors. Then the consumer will be alerted by differences in color to any improper substitution. Plaintiff's argument presupposes that the temptation to the pharmacists is so great and their propensity to commit crimes and violate their duties, both contractual and statutory, is so widespread that nothing short of granting plaintiff a monopoly over the red and blue colors will stem their wanton and extensive disregard of physicians' orders. In short, only the chance that a consumer aroused by receiving an unaccustomed color will complain is sufficient to deter pharmacists from pursuing their unscrupulous ways.

VI

In arguing for a monopoly of the red and blue shades plaintiff merely asserts an interest implicit in any claim for trademark infringement or unfair competition. To protect a trade name or symbol is to create or extend a monopoly. *Saxlehner v. Wagner*, 216 U.S. 375, 380, 30 S. Ct. 298, 54 L. Ed. 525 (1910) (per Holmes J.); *R.C.A. Manufacturing Co. v. Whiteman*, 114 F. 2d 86 (2d Cir.), *cert. den.* 311 U.S. 712, 61 S. Ct. 393, 85 L. Ed. 463 (1940); *Eastern Wine Corporation v. Winslow-Warren, Ltd.*, 137 F. 2d 955, 957 959 (2d Cir.), *cert. den.* 320 U.S. 758, 64 S. Ct. 65, 88 L. Ed. 452 (1943). But the law recognizes and approves monopolies of many kinds, of which patents, copyrights, and trademarks or trade names or symbols are but examples. Each serves some end sufficiently desirable to overcome the interest of society in unrestricted competition. Thus the law of trademarks and unfair competition when it secures to businesses the fruits of their initiative and enterprise is thought to encourage inventiveness, *Eastern Wine Corporation v. Winslow-Warren, Ltd., supra*, at 958, and to promote orderly and honest commercial practices, *Dwinell-Wright Co. v. White House Milk Co.*, 132 F. 2d 822, 825 (2d

Cir. 1948), and perhaps even morality and gentlemanliness. *Millinery Creators' Guild, Inc. v. F.T.C.*, 109 F. 2d 175, 177 (2d Cir. 1940), *aff'd*, 312 U.S. 469, 61 S. Ct. 708, 85 L. Ed. 955 (1941); *American Safety Table Co. v. Schreiber*, 269 F. 2d 255, 272, 273 (2d Cir.), *cert. den.*, 361 U.S. 915, 80 S. Ct. 259, 4 L. Ed. 2d 185 (1959). Moreover, by preventing one seller from misleading customers into believing that the goods come from another, the courts protect customers in their choices. *Benton Announcements, Inc. v. F.T.C.*, 130 F. 2d 254, 255 (2d Cir. 1942).

In each instance the determination to allow the exclusive use of a symbol requires a balancing of the interest in encouraging such values against the effect on consumers of whatever inhibition of competition may ensue. Where the balance has not been struck by legislation, *cf.* 15 U.S.C. §1057(b) (making a certificate of registration prima facie evidence of an exclusive right to use a trademark), the process will often require a court to weigh imponderables, and much can depend on which side must bear the burden of persuasion. As to that, two Supreme Court cases involving unfair competition, *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 84 S. Ct. 784, 11 L. Ed. 2d 661 (1964), and *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234, 84 S. Ct. 779, 11 L. Ed. 2d 669 (1964), give an unmistakable sign. Both cases involved deliberate and detailed copying of previously marketed products, and the Court ruled that it was not consistent with the policy of the patent provisions in the Constitution and the patent legislation for a state to prohibit the copying of an unpatented article. If, as the Court said in the *Compco Corp.* case, the "federal policy" found in Article I, section 8, clause 8 of the Constitution (giving Congress the power to promote science by securing to inventors for "limited" times the "exclusive" right to their discoveries) and in the implementing federal statutes is to allow "free access to

copy" whatever is left by them in the public domain, 376 U.S. at 237, 84 S. Ct. 779, then the presumption must be that competition shall be the general rule and limitations on it are exceptions requiring justification. As Mr. Justice Brandeis put it in *Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111, 122, 59 S. Ct. 109, 83 L. Ed. 73 (1938), "the consuming public is deeply interested" in the "free exercise" of the right to share in the goodwill of an article unprotected by a patent or a trademark. "[I]mitation is the life blood of competition." *American Safety Table Co. v. Schreiber, supra,* 269 F. 2d at 272. It follows that courts should be chary in granting judge-made monopolies which are both perpetual and unregulated. *Cheney Bros. v. Doris Silk Corp.*, 35 F. 2d 279, 281 (2d Cir. 1929) (per L. Hand, J.), *cert. den.*, 281 U.S. 728, 50 S. Ct. 245, 74 L. Ed. 1145 (1930).

With these principles in mind we turn to the several theories on which plaintiff seeks to obtain an injunction against defendants' practices.

VIII

Since it is the use of a "reproduction" or "copy" of a registered mark which Section 32 of the Lanham Act, 15 U.S.C. §1114, makes improper, plaintiff's claim of so-called "contributory" infringement of the trademark "Cyclospasmol" must be based on defendants' asserted inducement of the pharmacists not merely to substitute defendants' goods for plaintiff's but wrongfully to affix the "Cyclospasmol" label. No doubt the knowing and deliberate instigation of such a practice would justify holding defendants equally with the pharmacists as infringers. *Stix Products, Inc. v. United Merchants & Mfrs.*, 295 F. Supp. 479 (S.D.N.Y. 1968), is an example. There the defendant manufacturer conceived of using the infringing word in the retailers' advertising, paid for one half of their advertising

costs, and entered into hold harmless agreements with some retailers as to their use of the word. The product's assembler too was held as an infringer where it was aware of, participated in, and aided a promotional campaign to use the infringing word.

But here there is no showing that defendants have conspired with the pharmacists or counseled or suggested that they disregard the doctors' orders. As mentioned above, for a New York pharmacist to mislabel would put him at risk of criminal and civil penalties and would subject him to the loss of his license. Defendants' use of the blue and red colors, whatever its significance in assessing plaintiff's other claims, can hardly be deemed an invitation to the pharmacists to violate the penal law. A use of the same colors may make discovery of the offense less likely but it scarcely justifies holding defendants as accessories to the crime.

Before passage of the Lanham Act the doctrine of contributory trademark infringement went no further than to hold one who actively shared a retailer's infringement, as in the case, for example, of one who places the infringing label on the articles before delivering them to the retailer. *John B. Stetson Co. v. Stephen L. Stetson Co.*, 85 F. 2d 586, 588 (2d Cir.), *cert. den.* 299 U.S. 605, 57 S. Ct. 232, 81 L. Ed. 446 (1936); *Andrew Jergens Co. v. Bonded Products Corp.*, 21 F. 2d 419, 424 (2d Cir. 1927), *cert. den.* 275 U.S. 572, 48 S. Ct. 204, 72 L. Ed. 432 (1928); *Cuervo v. Jacob Henkell Co.*, 50 F. 471 (C.C.S.D.N.Y. 1892). Nothing in the language or history of Section 32 intimates that it was intended to expand the doctrine to embrace the mere copying of features not the subject of a mark.

Appendix A

IX

Plaintiff's other claim under the Lanham Act is based on Section 43(a), 15 U.S.C. §1125(a), which provides in pertinent part that anyone who affixes to or uses in connection with any goods or container for goods "a false designation of origin, or any false description or representation, including words or other symbols tending falsely to describe or represent" the goods, and causes them to enter commerce, shall be liable to a civil action by any person who believes he is or is likely to be damaged by the false description or representation.

Defendants' alleged false descriptions and representations are said to be of two kinds. First, plaintiff contends that defendants' advertisement of its cyclandelate as "comparable" or "equivalent" to "Cyclospasmol" is false. Second, plaintiff argues that the copying of its colors is an implied representation that the product comes from plaintiff.

The former contention has not been established by plaintiff. For purposes of the motion plaintiff has conceded that the two products have the same bioavailability and are bioequivalent. One would ordinarily suppose that to recite that a drug is "comparable" or "equivalent" to that of another is to convey the impression that its effect on the consumer is comparable or equivalent. Plaintiff submits no evidence that defendants' product is unsafe or affects patients differently from "Cyclospasmol".

Plaintiff nonetheless says that defendants may not call their product comparable or equivalent because they have not received approval from the Federal Food and Drug Administration ("FDA") to market their product whereas plaintiff has. Defendants claim that the FDA has informed them

they do not need such approval. It is not clear to what extent plaintiff challenges this assertion, but, assuming the matter to be relevant at all (*see* §307 of the Food, Drug and Cosmetic Act, 21 U.S.C. §337, requiring proceedings to enforce the act to be brought in the name of the United States), at best an issue of fact would be raised as to whether defendants were required by the FDA to obtain approval.

The contention that defendants' use of the red and blue colors is a "false designation of origin" or a "false description or representation" within the meaning of Section 43(a) assumes that the colors have come to symbolize not only the product but also the producer (or at least the one who gives assurance of the product's quality.)[2] Plaintiff argues, in effect, that the colors are to be taken as representing to the patient "this will not only have the same therapeutic effect on you as Cyclospasmol, an Ives product, that you have been taking; it is in fact Ives' Cyclospasmol." Thus, says plaintiff, a use of the colors on a product equivalent to that of plaintiff but not made by it constitutes a misrepresentation though plaintiff has no patent and no trademark on the colors. It does not matter, of course, that no words articulated the alleged representation. Section 43(a) contemplates that "symbols" may falsely describe a product.

But this is not the typical "palming off" case where those who make the choice are said to be deceived. Here the patient ordinarily does not choose what drug to use or whether to buy a brand name or a generic drug. The doctors make that choice, and

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2. Since 15 U.S.C. §1060 permits an assignment of a registered mark provided the licensor supervises the licensee's use, *Dawn Donut Co. v. Hart's Food Stores, Inc.*, 267 F. 2d 358, 366, 367 (2d Cir. 1959), a trademark may not necessarily symbolize the origin of the goods.

they are under no illusion that defendants' product is that of plaintiff. Consequently the significance to the consumers of the colors is not to symbolize the source of the goods so as to enable them to discriminate between competing producers. In the prescription drug context colors serve for the consumers other purposes of which plaintiff claims one should be to alert them to unscrupulous substitutions by pharmacists. Whatever "damage" plaintiff suffers occurs because defendants use colors not likely to arouse the consumers to an illegal substitution by the pharmacist. Plaintiff therefore contends that it is a "false representation" under Section 43(a) for anyone to color their capsules like those of plaintiff, and it should be granted exclusive use of red and blue.

In determining whether or to what extent Section 43(a) accords exclusive use of colors to a business *Sears, Roebuck & Co. v. Stiffel Company, supra,* 376 U.S. 225, 84 S. Ct. 784, 11 L. Ed. 2d 661 (1964); and *Compco Corp. v. Day-Brite Lighting, Inc., supra,* 376 U.S. 234, 84 S. Ct. 779, 11 L. Ed. 2d 669 (1964), must be considered. Both involved state unfair competition laws which the lower courts had used to prevent copying of unpatented designs, in one case of a "pole lamp" and in the other of a fluorescent lighting reflector. As described above, the Supreme Court held that a state's unfair competition law could not, consistently with the implication of the patent laws, prohibit copying of the designs. In the *Sears* case the court described the limitations imposed on the power of the states in the following terms:

> "Of course there could be 'confusion' as to who had manufactured these nearly identical articles. But mere inability of the public to tell two identical articles apart is not enough to support an injunction against copying or an

> award of damages for copying that which the federal patent laws permit to be copied. Doubtless a State may, in appropriate circumstances, require that goods, whether patented or unpatented, be labelled or that other precautionary steps be taken to prevent customers from being misled as to the source, just as it may protect businesses in the use of their trademarks, labels, or distinctive dress in the packaging of goods so as to prevent others, by imitating such markings, from misleading purchasers as to the source of the goods. But because of the federal patent laws a State may not, when the article is unpatented and uncopyrighted, prohibit the copying of the article itself or award damages for such copying." [Footnote omitted]

376 U.S. at 232 33, 84 S. Ct. at 789.

And in the *Compco Corp.* case the Court explained further:

> "As we have said in *Sears*, while the federal patent laws prevent a State from prohibiting the copying and selling of unpatented articles, they do not stand in the way of state law, statutory or decisional, which requires those who make and sell copies to take precautions to identify their products as their own. A State of course has power to impose liability upon those who, knowing that the public is relying upon an original manufacturer's reputation for quality and integrity, deceive the public by palming off their copies as the original. That an article copied

> from an unpatented article could be made in some other way, that the design is 'nonfunctional' and not essential to the use of either article, that the configuration of the article copied may have a 'secondary meaning' which identifies the maker to the trade, or that there may be 'confusion' among purchasers as to which article is which or as to who is the maker, may be relevant evidence in applying a State's law requiring such precautions as labeling; however, and regardless of the copier's motives, neither these facts nor any others can furnish a basis for imposing liability for or prohibiting the actual acts of copying and selling. *Cf. Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111, 120, 59 S. Ct. 109, 114, 83 L. Ed. 73 (1938). And of course a State cannot hold a copier accountable in damages for failure to label or otherwise to identify his goods unless his failure is in violation of valid state statutory or decisional law requiring the copier to label or take other precautions to prevent confusion of customers as to the source of the goods." [Footnote omitted]

376 U.S. at 238-39, 84 S. Ct. at 782.

Both Supreme Court decisions dealt with the copying of physical designs, and the opinions make no mention of colors. But the means allowed to a state to prevent "palming off" were sharply restricted. Although the state could require labeling and prohibit imitation of a "marking" or "distinctive dress in the packaging of goods" so that purchasers would not be mislead as to the source, even a design's "nonfunctional" aspect which had acquired a "secondary meaning" could not be protected. It is

thus hard to believe that the Supreme Court would consider that colors, or at least those not so fancifully or ingeniously arranged as to be eligible for registration as a trademark, can constitute a "label" or "marking" so as to qualify for the exclusive use of one business. Certainly the blue and red colors used by plaintiff cannot be deemed "distinctive dress in the packaging of goods". The capsules are not part of the "packaging". They are ingested by the patient and are the "goods" themselves. The language of the *Sears* and *Compco Corp.* cases, if taken at face value, thus appears to preclude any claim that defendants engaged in "unfair competition" by using capsules colored red and blue.

These decisions addressed themselves to the federal limitations on state unfair competition laws. So far as the opinions reveal, no consideration was given to whether Section 43(a) of the Lanham Act created a federal unfair competition law as to palming off broader than that permissible to the states. However, nothing in the Act's legislative history has been cited to this court and no policy is apparent suggesting that Congress had such an intention. The reasoning of the *Sears* and *Compco Corp.* cases would thus appear to be applicable to a Section 43(a) claim.

It is suggested that the quoted language from the *Sears* and *Compco Corp.* opinions is mere dictum which should not be followed in an action for unfair competition or for violation of Section 43(a) of the Lanham Act. Indeed, the Court of Appeals for the Eighth Circuit so held in a case brought under Section 43(a). *Truck Equipment Serv. Co. v. Fruchauf Corp.*, 536 F. 2d 1210, 1214, 1215 (8th Cir.), *cert. den.*, 429 U.S. 861, 97 S. Ct. 164, 50 L. Ed. 2d 139 (1976). There the defendant decided to enter into the hopper grain trailer market and copied plaintiff's design, portions of which the court found to be "nonfunctional"

and to have acquired a "secondary meaning". Defendant also used in its sales promotion literature photographs of plaintiff's trailer. The court held that the use of the photographs constituted a "false designation of origin" within the meaning of Section 43(a). The court also appears to have held the sales of the trailers themselves to be violations of Section 43(a) because by copying the nonfunctional portion of the design defendants had misbranded their product as that of plaintiff. 536 F. 2d at 1216. The court in interpreting Section 43(a) used the old tests of "unfair competition" which the *Sears* and *Compco Corp.* opinions had deemed impermissible, namely, whether features of the product were "nonfunctional", if so whether they had acquired a "secondary meaning", and whether their use by another was likely to cause "confusion" among purchasers.

No such restrictive reading of the two Supreme Court opinions has as yet been embraced in the Second Circuit. In *Bose Corporation v. Linear Design Labs, Inc.*, 467 F. 2d 304 (2d Cir. 1972), the court had before it a loudspeaker system of a unique pentagonal shape which plaintiff deliberately marketed without affixing its name, relying on the uniqueness of the product design to establish a common law trademark showing the product's origin as plaintiff. The defendant copied the design, and plaintiff claimed this was a false representation of origin under Section 43(a). The court left open the possibility that "product appearance, in its non-functional aspects, can support a holding under §43(a) of the Lanham Act that the design functions as a[n][unregistered] trademark to indicate origin, if it has acquired a secondary meaning[.]" 467 F. 2d at 309. The court said it was unnecessary to decide whether this "purported simulation of trade dress" could give rise to a claim under Section 43(a). 467 F. 2d at 310. *Cf. Sutton Cosmetics (P.R.) v. Lander Co.*, 455 F. 2d 285 (2d Cir. 1972) (Section 43(a)

prohibits deliberate copying of a competitor's trademark and packaging design for cosmetics).

Two years later, without referring to the *Bose* case, the Second Circuit read Section 43(a) as not going so far as to require "those who purvey goods to make affirmative disclosures about those goods where necessary to prevent the deception of the purchaser." *Alfred Dunhill Limited v. Interstate Cigar Company, Inc.*, 499 F. 2d 232, 237, 238 (2d Cir. 1974). There Alfred Dunhill Limited sought to enjoin defendant from selling salvaged Dunhill brand tobacco under the Dunhill trademark without labelling it as subjected to possible water damage. The court held that there was no violation of Section 43(a), which "does not have boundless application as a remedy for unfair trade practices but is limited to false advertising as that term is generally understood." 499 F. 2d at 237.

In the light of these two opinions it is at best uncertain whether a claim may be made in this circuit under Section 43(a) based on "trade dress" or whether the Court of Appeals for the Second Circuit would agree with the Eighth Circuit in considering the quoted language of the *Sears* and *Compco Corp.* cases as not binding. It is not necessary now to decide that question or to assess the considerations which led the Supreme Court opinions to abandon as unfruitful the distinction between "functional" and "nonfunctional" aspects of a product. For even if Section 43(a) be deemed to have enacted a federal law of "unfair competition" so as to prohibit the copying of a product's "nonfunctional" features which have acquired a "secondary meaning", plaintiff is not entitled to a preliminary injunction.

First, plaintiff has not established that the colors are "nonfunctional". Assuming they have no direct physical healing value, they serve purposes other than to identify plaintiff as the

source. While we need not now consider the extent, if any, to which the use of a brand name during the life of a patent on a unique product causes that name to become generic and unprotectable when the patent expires, certainly the pale blue in which the 200 mg. capsules of Cyclospasmol were sold during the patent period may, in the case of some patients, have come to symbolize not merely the source but also the drug itself and its therapeutic effects. The drug could be obtained only from plaintiff during the term of the patent, and to the extent that the blue color represents to the consumer the chemical ingredients which offer relief it would be an extension of the patent monopoly beyond its term to grant plaintiff the perpetual and exclusive use of the unpatented color.

The blue and red shades of the 400 mg. capsules marketed first in 1975 have had a lesser time to acquire a symbolic therapeutic meaning to consumers. But here too there is no reason to suppose the colors have no function other than to identify plaintiff. Courts have never looked with favor on a demand to monopolize colors, *A. Leschen & Sons Rope Company v. Broderick & Bascom Rope Company*, 201 U.S. 166, 171, 172, 26 S. Ct. 425, 50 L. Ed. 710 (1906), and the blue and red used by plaintiff are no less functional than the pink color which the Second Circuit would not allow to be appropriated by the maker of "Pepto-Bismol". *Norwich Pharmacal Company v. Sterling Drug Co.*, 271 F. 2d 569 (2d Cir. 1959). Here, as there, it is plausible to infer that the color may present "a pleasing appearance to the customer and to the sufferer." 271 F. 2d at 572. In each case the consumer may associate the color with a beneficent effect. In any event it is fair to conclude, as defendants argue, that some patients may be fearful and offer resistance if their accustomed medication is dispensed in a different color.

Defendants argue that the colors have other functions, for example, to identify a drug in an emergency situation where an overdose is suspected. While this would plainly not be a preferred method of identification, perhaps in some situations it will be all that is immediately available, and to that extent the colors serve a practical purpose. Defendants also say that a patient may be taking several different drugs and may determine which ones to take and when by the colors. This hardly seems the most cautious way in which to take medication. But the law must recognize that individuals differ, and that to some the colors may be a signal and a protection.

Even assuming the colors to be "nonfunctional", plaintiff has not established that they have a "secondary meaning" identifying the product's source because of which consumers are moved to purchase. *Blisscraft of Hollywood v. United Plastics Co.*, 294 F.2d 694 (2d Cir. 1961).[3] Indeed, plaintiff has agreed not to rely on secondary meaning for purposes of the motion except to argue that defendants' copying in itself constitutes "evidence" of secondary meaning. No doubt copying of packaging can give rise to an inference that it has acquired a secondary meaning where no reasonable conclusion can be drawn other than that the defendant sought to pretend his goods were those of plaintiff's. *Scholl, Inc. v. Tops E.H.R. Corp.*, 185 U.S. P.Q. 754 (E.D.N.Y. 1975). But no such conclusion is

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3. Plaintiff argues that it can prevail without showing "secondary meaning" provided it can show "palming off". Doubtless where there is imitation of a trade name the use of the same colors might be "an intrinsic element" of the palming off. *Pro-phy-lac-tic Brush Co. v. Abraham & Straus*, 11 F. Supp. 660, 664 (E.D.N.Y. 1935). Where there is no copying of a trade name or the packaging but an unpatented feature of the product itself is sought to be monopolized that feature must at least have acquired a "secondary meaning". *Bose Corporation v. Linear Design, Labs, Inc., supra.*

inevitable here. Defendants could reasonably have believed that the colors represented to the patient the therapeutic properties of cyclandelate.

Finally, this is a court of equity, cautioned to be wary of granting everlasting and unsupervised monopolies. It must consider the purpose which would be served by giving one business exclusive use of blue and red and must determine whether that end can be attained by means less drastic and more suited to a competitive economy.

As mentioned, plaintiff seeks to monopolize the colors in the hope the consumers will help identify dishonest druggists. No conclusive proof has been submitted as to the extent to which this would occur, though it may be assumed that some pharmacists with fraudulent intent would be deterred if differing colors were required.

But this is not the only method of policing pharmacists. Plaintiff and the State of New York are not without resources to identify, pursue and bring to justice pharmacists who are violating their duties. In preparation for this motion plaintiff has made test purchases in New York and other states to determine whether there have been illegal substitutions. Indeed, it appears that plaintiff has knowledge of drug stores that have a proclivity toward illegal substitution. Plaintiff can bring proceedings against them, as has been done in the case of Lowitt, and can also report the violations to the state authorities for criminal prosecution, for the collection of civil monetary penalties, and for proceedings to revoke the pharmacists' licenses. Successful efforts along these lines may well have the desired general deterrent effect.

In addition, the physicians, who have been the target of plaintiff's massive promotional campaigns and who as a group are not notoriously unsympathetic to the manufacturers of brand name drugs, have it in their power to alert their patients to look for the "Ives" imprint on the capsules.

Considering all these factors the court holds that on the present papers plaintiff has not shown a violation of Section 43(a).

X

Little need be added concerning the "unfair competition" claim under New York law. The limitations imposed by the *Sears* and *Compco Corp.* opinions have already been discussed.

To the extent that New York is free to impose requirements to prevent customers from being misled as to the source of goods New York law appears to follow principles no more expansive than those adopted generally by federal and state courts. Moreover, the New York Education Law, by requiring a line on the prescription form permitting a druggist to substitute an appropriate lower priced drug, has manifested a positive policy to encourage legal substitutions and has thus added an additional consideration to the balance. For reasons already stated it is at least possible that giving plaintiff exclusive use of red and blue will inhibit legitimate substitutions which the New York legislature has found to be in the public interest.

Plaintiff has cited no authority persuasive that New York law entitles it to relief. *E.R. Squibb & Sons, Inc. v. Premo Pharmaceutical Labs, Inc.*, 195 U.S.P.Q. 545 (S.D.N.Y. 1977), although it involved a prescription drug and applied New York law, concerned the imitation of the "get-up" of the

manufacturer's packaging carton, which the pharmacist dispensed to the customer, and not a copy of the drug tablet itself. In *Marion Laboratories, Inc. v. Michigan Pharmacal Corp.*, 338 F. Supp. 762 (E.D. Mich. 1972), *aff'd* without opinion 473 F. 2d 910 (6th Cir. 1973), also a prescription drug case, the court applied the Michigan law of unfair competition, and held for the defendant, finding it had not induced pharmacists to substitute.

Merrell-National Laboratories v. Zenith Laboratories, 194 U.S.P.Q. 157 (D.N.J. 1977), appeal from injunctive order dismissed on procedural grounds, appeal from order denying motion for redetermination affirmed, 579 F.2d 786 (3rd Cir. 1978), is more directly in point. Applying New Jersey unfair competition law the court preliminarily enjoined the defendants from copying the physical appearance and colors of the plaintiff's prescription drug tablets. In that case the defendants did not submit factual affidavits opposing the preliminary injunction until they applied for "re-determination" of the motion. Only then did they set forth facts showing that the color and shape of the tablets had functional characteristics. Apparently the District Court denied redetermination in part because the belatedly offered facts had been known to the defendants when the original motion was made. The District Court opinion is therefore a dubious precedent. To the extent that its language is inconsistent with the result reached in the case at bar, this court respectfully disagrees.

Finally, plaintiff does not claim that Section 368 d of the New York General Business Law affords any broader support for its position than New York's common law of unfair competition. The Section provides in substance that likelihood of injury to business reputation or of dilution of the distinctive quality of a mark or trade name shall be ground for injunctive

relief in cases of infringement of a mark or unfair competition notwithstanding the absence of competition or confusion as to the source of the goods.

The section was apparently designed to permit injunctions in trademark, trade name and unfair competition cases where the defendant was engaged in a category of business different from that of plaintiff. *Cf. Federal Telephone & R. Corp. v. Federal Television Corp.* 180 F.2d 250, 251, 252 (2d Cir. 1950). The language has apparently never been read to expand the law of unfair competition as applied to competitors.

XI

Except for the claim of trademarks infringement against Sherry, none of plaintiff's contentions has sufficient merit to warrant issuance of a preliminary injunction. Settle order.

APPENDIX B — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT, *IVES LABORATORIES, INC. v. DARBY DRUG CO., INC.*, 601 F. 2d 631 (2D CIR. 1979)

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

No. 529—August Term, 1978.

(Argued May 2, 1979 Decided June 11, 1979.)

Docket No. 78-7454

IVES LABORATORIES, INC.,

Plaintiff-Appellant,

—v.—

DARBY DRUG CO., INC., INWOOD LABORATORIES INCORPORATED, LOWITT LABS ., INC., MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,

Defendants-Appellees.

Before:

FRIENDLY and MULLIGAN, *Circuit Judges,* and GAGLIARDI, *District Judge.* *

Appeal from an order of the District Court for the Eastern District of New York, Eugene H. Nickerson, *Judge,* 455 F.Supp. 939 (E.D.N.Y. 1978), denying plain-

* Judge of the United States District Court for the Southern District of New York, sitting by designation.

tiff's motion for a preliminary injunction against defendants' manufacturing and selling capsules of cyclandelate powder identical in color and size with those marketed by plaintiff under its registered trademark "Cyclospasmol." Affirmed, with instructions.

MARIE V. DRISCOLL, Esq., New York, N.Y. (Rogers, Hoge & Hills, New York, N.Y., William F. Weigel, Esq., Charles J. Raubicheck, Esq., Egon E. Berg, Esq., and Steven Baron, Esq., Of Counsel), *for Plaintiff-Appellant, Ives Laboratories, Inc.*

ROBERT V. MARROW, Esq., New York, N.Y. (Salon, Bloustein & Raybin, New York, N.Y., Leon Salon, Esq. and Lauren Friedman, Esq., Of Counsel), *for Defendants-Appellees, Darby Drug Co., Inc., MD Pharmaceutical Company, Inc., Rugby Laboratories, Inc., and Sherry Pharmaceutical Co., Inc.*

SHELDON S. LUSTIGMAN, Esq., New York, N.Y. (Bass, Uliman & Lustigman, New York, N.Y.), *for Defendant-Appellee, Inwood Laboratories Incorporated.*

PETER T. COBRIN, Esq., New York, N.Y. (Kirschstein, Kirschstein, Ottinger & Cobrin, P.C., New York, N.Y., David B. Kirschstein, Esq., Of Counsel), *for Defendant-Appellee Premo Pharmaceutical Laboratories, Inc.*

Appendix B

JOHN H. SHENEFIELD, Esq., Assistant Attorney General, United States Department of Justice, Washington, D.C., Barry Grossman, Esq., Roger B. Andewelt, Esq., Robert J. Wiggers, Esq., and Andrew L. Pringle, Esq., Attorneys, Department of Justice, Of Counsel), *for the United States as Amicus Curiae.*

FRIENDLY, *Circuit Judge:*

This appeal from an order of the District Court for the Eastern District of New York denying a motion of plaintiff, Ives Laboratories, Inc., for a preliminary injunction, 455 F.Supp. 939 (1978), raises interesting questions of the application of *Sears, Roebuck & Co. v. Stiffel Company,* 376 U.S. 225 (1964) and *Compco Corp. v. Day-Brite Lighting, Inc.,* 376 U.S. 234 (1964), to the imitation of a peripheral vasodilator, dispensed only on a physician's prescription, once covered by a patent now expired and still covered by a registered trademark "Cyclospasmol". Although we find the case more difficult that did the district judge, we affirm the denial of a temporary injunction as within the discretion accorded to him.

I.

Plaintiff Ives Laboratories, Inc. (Ives) manufactures and sells Cyclospasmol to wholesalers, retail pharmacists, and hospitals. The drug, a powder whose generic name is cyclandelate, is sold in two kinds of labeled packages. One type of package is filled with pale blue capsules imprinted "Ives 4124", each containing a dosage of 200 mg. The other is filled with red-and-blue capsules imprinted "Ives

4148", each containing a dosage of 400 mg. The blue capsule had been used during the life of the patent; the blue-and-red capsule was introduced after its expiration.

Ives directs its advertising not to the consumer but to prescribing physicians and to pharmacists in hospitals and elsewhere. Until April 26, 1972, when the patent expired, the primary object of the advertising (which included the large-scale distribution of "starter" samples) was to convince the physician of the superiority of Cyclospasmol over other vasodilators; since then the advertising has had the additional objective of persuading the physician to specify Cyclospasmol rather than writing prescriptions which can be filled with competing cyclandelate preparations. The latter objective has assumed increased importance because of the enactment of "generic drug laws" by many states.[1]

Defendants Premo Pharmaceutical Laboratories, Inc. (Premo), Inwood Laboratories, Incorporated (Inwood), and MD Pharmaceutical Company, Inc. (MD), (collectively the manufacturers), purchase empty capsules which they fill with the cyclandelate powder and sell the capsules to

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1 The New York law, Education Law § 6810(6)(a), requires the prescription form to state:

> This prescription will be filled generically unless physician signs on line stating "dispense as written."

The form must contain two lines, one over the words "substitution permissible" and the other over the words "dispense as written"; the physician must sign one or the other. If the physician signs the "substitution permissible" line, substitution is mandatory if the drug is on a list established under the New York Health Law, see N.Y. Education Law § 6816-a, N.Y. Public Health Laws § 206(1)(i); in other cases substitution of the generic drug is permissible. Unless the physician otherwise directs, the pharmacist making a substitution must indicate on the label the name and strength of the drug and its manufacturer; when a brand name is dispensed, the pharmacist, unless otherwise directed by the prescription, must similarly affix on the label the brand name and strength. N.Y. Education Law § 6816-a.

wholesalers, hospitals, retail pharmacies and others. Premo and Inwood manufacture and sell both 200 mg. and 400 mg. capsules in colors essentially identical to Ives'; MD has done the same with 200 mg. capsules. Until shortly before the district court's decision, none imprinted any mark on their capsules; on June 26, 1978, Premo filed an affidavit stating that in the future it would imprint "Premo" on all its capsules. Three other defendants, Darby Drug Co., Inc. (Darby); Rugby Laboratories, Inc. (Rugby); and Sherry Pharmaceutical Co., Inc. (Sherry), (collectively "the wholesalers") purchase capsules of the sort described and resell them to other wholesalers, doctors, pharmacies and others. Both categories of defendants promote the generic product as "comparable" or "similar" or "equivalent" to Cyclospasmol; in some catalogs they refer to the color of the capsules.[2] Defendants' advertising, like plaintiff's, is directed to physicians, pharmacists, and other intermediaries, and not to the ultimate consumer. Ives conceded for the purpose of the temporary injunction motion that the cyclandelate used by defendants had the same therapeutic properties as that used in Cyclospasmol.

The complaint claimed that defendants' use of capsules having the same color or colors as those previously adopted by Ives violated its rights in three ways:

(1) as contributory infringements in violation of § 32 of the Lanham Act, 15 U.S.C. § 1114, in that the

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2 Sherry had offered the drug under the name "Spasmol" but had abandoned such use. The district court enjoined resumption of the practice, and Sherry has not appealed. Plaintiff had also named an additional defendant, Lowitt Labs Inc. (Lowitt), a retail pharmacy; the complaint charged that, on receiving a prescription for Cyclospasmol, Lowitt substituted generic cyclandelate and labeled the bottle "Cyclospasmol." The court entered a consent order prohibiting this.

similarity encouraged retail druggists to use Ives' mark "Cyclospasmol" in selling capsules not manufactured by it;

(2) as "a false designation of origin, or any false description or representation, including words or other symbols tending falsely to describe or represent" the goods sold by defendants in violation of § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a);[3]

(3) as unfair competition under New York common and statutory law, N.Y. General Business Law § 368-d.

In a considered opinion, 455 F.Supp. 939, Judge Nickerson found that there was no sufficient evidence that defendants had been encouraging, as distinguished from merely facilitating, druggists in using Ives' mark in prescriptions filled with generic cyclandelate, and that the other claims were probably invalid, either because of the "general" law of trademarks and unfair competition or as contravening *Sears* and *Compco*. In his view, therefore, "none of plaintiff's contentions has sufficient merit to warrant issuance of a preliminary injunction." *Id.* at 952.[4]

Ives' complaint related to a wide spectrum of acts. In a state with a generic drug law like New York's these range

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3 In the trial court this claim included a contention that the product sold by defendants was not "comparable" or "equivalent" to Cyclospasmol. The judge held this claim not to have been proved, 455 F.Supp. at 946, and the contention has not been pressed on this appeal from the denial of a temporary injunction.

4 The judge referred to our formulation of the criterion for this in *Selchow & Righter Co. v. McGraw-Hill Book Company*, 580 F.2d 25, 27 (1978). Since we think it clear that Ives showed "irreparable injury" at least in the sense of impracticability of establishing the amount of damages, we must assume that the judge concluded that there was no probability of success on the merits and *either* that the questions raised by plaintiff were not sufficiently serious to make them a fair ground for litigation *or* that the balance of hardships did not tip decidedly in its favor.

from the most serious case, where the physician has specified Cyclospasmol and the druggist has filled the prescription with the generic product but has labeled it "Cyclospasmol"—admittedly actionable against the druggist—to the most innocent one, where the physician has permitted substitution and the druggist has filled the prescription with capsules of the competing manufacturer and so labeled the package. Intermediate cases are where the prescription requires Cyclospasmol and the druggist substitutes a product of the defendants naming it or not, and where the prescription permits substitution and the druggist fills it with defendant's product but names it Cyclospasmol (again clearly actionable against the druggist) or gives no name at all.[5] Similar variations can occur in other states with or without generic drug laws.

II.

It will be useful to discuss at the outset plaintiff's claim of contributory infringement in violation of § 32 of the Lanham Act, 15 U.S.C. § 1114. The judge was right in concluding that the protection conferred by that section is narrower than that afforded by § 43(a), 15 U.S.C. § 1125(a), in that the former relates only to infringement of the trademark itself and thus would apply only to cases where Ives' mark or a confusingly similar one had been used. We fear, however, that his approach to the issue may have been unduly narrow. He referred to "the knowing and deliberate instigation of such a practice", 455 F.Supp. at 945, and said that before "passage of the

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5 While many of these variations are actionable as misbranding under the New York law, see N.Y. Education Law §§ 6811(a), 6815(2)(h), 6816, these laws, aimed at protecting the consumer, do not necessarily displace the protection for competitors embodied in trademark and unfair competition law.

Lanham Act the doctrine of contributory trademark infringement went no further than to hold one who actively shared a retailer's infringement, as in the case, for example, of one who places the infringing label on the articles before delivering them to the retailer." *Id.* at 946, citing cases. While such cases would surely constitute contributory infringement, they do not mark the limits of the doctrine. The authorities later reviewed indicate to us that a manufacturer or wholesaler would be liable under § 32 if he suggested, even if only by implication, that a retailer fill a bottle with the generic capsules and apply Ives' mark to the label, or continued to sell capsules containing the generic drug which facilitated this to a druggist whom he knew or had reason to know was engaging in the practices just described. The proper criteria are stated in *Coca-Cola Co. v. Snow Crest Beverages, Inc.*, 64 F.Supp. 980, 989 (D. Mass. 1946) (Wyzanski, J.), affd., 162 F.2d 280 (1 Cir.), *cert. denied*, 332 U.S. 809 (1947). As will be shown below, nothing in *Sears* or *Compco* allows such practices. If the judge considered a narrower view of the doctrine of contributory infringement to be warranted because mislabeling by a New York pharmacist "would put him at risk of criminal and civil penalties and would subject him to the loss of his license" and thought that defendants would be liable for contributory infringement only if they could be held "as accessories to the crime", 455 F.Supp. at 945-46, he was in error. New York's provision of additional sanctions for confusing consumers by infringement of a trademark cannot limit the rights bestowed by federal law. However, the court was justified in concluding that Ives failed to adduce the quantum of proof necessary to require issuance of a temporary injunction for contributory infringement even on what we deem the proper standard of liability under § 32.

Ives' proof was limited to 15 instances of improper substitution and defendants conceded only that the identity of color made this easier if a druggist were so inclined.

III.

Before considering Ives' other claims, it will be useful to review what we regard as the most pertinent authorities.

We begin with two opinions of the Supreme Court. *William R. Warner & Co. v. Eli Lilly & Co.*, 265 U.S. 526 (1924), was a prescription drug case with facts close to those here.[6] Lilly had begun and continued to make and sell an unpatented prescription liquid preparation of quinine in combination with other substances, including yerba-santa and chocolate, under the name of Coco-Quinine. Predecessors of Warner later marketed a similar preparation under the name of Quin-Coco. Lilly sued for trademark infringement and unfair competition. The Court agreed with the two lower courts in dismissing the claim of trademark infringement on the ground that both names were descriptive. On the issue of unfair competition the Court held that Lilly had no right to prevent Warner from manufacturing and selling a product exactly like Coco-Quinine. That, however, was far from ending the case. The Court mentioned with disapproval that some of Warner's salesmen "suggested that, without danger of detection, prescriptions and orders for Coco-Quinine could be filled by substituting Quin-Coco" and that "[m]ore often . . . the feasibility of such a course was brought to the mind of the druggist by pointing out the identity of the two preparations and the enhanced

6 Although the opinion does not say so, the Court apparently applied its own views of trademark and unfair competition law under the principle of *Swift v. Tyson*, 41 U.S. (16 Pet.) 1 (1842).

profit to be made by selling Quin-Coco because of its lower price." 265 U.S. at 530. "That no deception was practiced on the retail dealers, and that they knew exactly what they were getting is of no consequence. The wrong was in designedly enabling the dealers to palm off the preparation as that of the respondent." *Id.* While Lilly was not entitled to the injunction granted by the court of appeals which enjoined Warner from the use of chocolate, it was entitled to "effective relief". This should include not only prohibition of acts such as those above recited but also a requirement that the packages sold the druggists "shall not only bear labels clearly distinguishing petitioner's [Warner's] bottled product from the bottled product of respondent [Lilly], but that these labels shall state affirmatively that the preparation is not to be sold or dispensed as Coco-Quinine or be used in filling prescriptions or orders calling for the latter." 265 U.S. at 532-33.

The second case, *Kellogg Company v. National Biscuit Co.*, 305 U.S. 111 (1938),[7] related to shredded wheat. The product had been originated by National's predecessor, one Perky, who had obtained a patent on the machine used in its manufacture. National marketed the product, in a pillow-shaped form, under the name of Shredded Wheat in packages picturing a dish containing two biscuits submerged in milk. Kellogg manufactured and sold a similar product under the same name, shredded wheat. After procedural complications unnecessary to detail, the Court of Appeals for the Third Circuit directed the district court to enter a decree, 96 F.2d 873 (1938), enjoining Kellogg:

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7 Mr. Justice Brandeis noted, 305 U.S. at 113 n. 1, that "[m]ost of the issues in the case involve questions of common law and hence are within the scope of *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938). But no claim has been made that the local law is any different from the general law on the subject, and both parties have relied almost entirely on federal precedents."

(1) from the use of the name 'SHREDDED WHEAT' as its trade name, (2) from advertising or offering for sale its product in the form and shape of plaintiff's biscuit, and (3) from doing either.

305 U.S. at 115.

In reversing, the Supreme Court began by holding that National had no exclusive right to Shredded Wheat as a trade name both because the term was generic and because the name "as well as the product, the process and the machinery employed in making it, has been dedicated to the public" upon the expiration of Perky's patent in 1912 or shortly thereafter. Because National had allowed Shredded Wheat to become "the generic designation of the thing which has arisen during the [patent] monopoly," *Singer Mfg. Co. v. June Mfg. Co.*, 163 U.S. 169, 185 (1896), it would in effect extend the patent monopoly if National were to be given exclusive rights in the name.

The Court next held that National "has not the exclusive right to sell shredded wheat in the form of a pillow-shaped biscuit . . . ." This was primarily because the pillow shape was that in which shredded wheat was made under the patent. Here again Kellogg "was free to use the pillow-shaped form, subject only to the obligation to identify its product lest it be mistaken for that of the plaintiff." 305 U.S. at 120.

Finally the Court addressed itself to the question whether Kellogg was exercising its rights "fairly", i.e., "in a manner which reasonably distinguishes its product from that of plaintiff." It found that Kellogg had taken every reasonable means for doing this—using cartons distinctive in size, form and color, featuring the name Kellogg, and containing biscuits only two-thirds the size of National's. Conceding that Kellogg was sharing in the good-will of an article created by National and its predecessors, Mr.

Justice Brandeis said that "[s]haring in the goodwill of an article unprotected by patent or trademark is the exercise of a right possessed by all—and in the free exercise of which the consuming public is deeply interested." 305 U.S. at 122.

There is something for everyone in these two decisions. Defendants take comfort from so much of *Warner* as upheld that company's right to copy not only the basic ingredients of Lilly's product but their color, taste and smell; plaintiff emphasizes the severe restrictions placed on Warner in order to avoid dishonest substitution by druggists. Defendants find cheer in the holdings in *Kellogg* that National, in part because of expiration of the patent, had no rights in the name Shredded Wheat or in the pillow-shaped form. Plaintiff says that the holding as to the name was based on its generic nature; that the Court differentiated the case of a valid trademark; that the holding as to the pillow-shaped form likewise was predicated on the bases that this was what the patented machine was designed to produce and that the form was also covered by a design patent that had been held invalid and in any event had long since expired; and that, even on the premise that neither the name nor the form deserved protection, the Court still insisted on Kellogg's doing everything reasonably possible to disclose the difference in source. It argues that here in contrast, so far as the ultimate consumer is concerned, the defendants did nothing (except for Premo's recent imprinting) to disclose the difference to the consumer, although the use of other colors was entirely feasible.

We turn next to a few particularly pertinent decisions of courts of appeals in the interval between *Kellogg* and *Sears-Compco*—one before and the others after the effective date of the Lanham Act. *Smith, Kline & French*

Laboratories v. Clark & Clark, 157 F.2d 725 (3 Cir.), *cert. denied*, 329 U.S. 796 (1946), involved both patent and unfair competition claims relating to amphetamine sulphate tablets, a prescription drug. The court found that the shape, color and scoring of the tablets were functional. Partially reversing a decree perpetually enjoining Clark & Clark from manufacturing or selling these, the court held that SKF was entitled to such an injunction only during its patent monopoly and thereafter "to a decree enjoining the palming off of the defendants' product for that of SKF." This should include "[a] provision requiring the defendants to stamp their tablets with the initials C & C or some other distinguishing mark . . ." (footnote omitted), 157 F.2d at 731.[8]

Upjohn Company v. Schwartz, 246 F.2d 254 (2 Cir. 1957), also has some factual resemblance to this case. The portion of the opinion here relevant is that dealing with the prescription trade in various unpatented tablets

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8 Previous discussion in the opinion indicated that the injunction should also include a prohibition against defendant's salesmen pointing out the feasibility of substituting defendant's product for SKF's without danger of detection, 157 F.2d at 731.

Smith, Kline & French Laboratories v. Heart Pharmaceutical Corp., 90 F.Supp. 976 (S.D.N.Y. 1950), citing *Clark & Clark*, accorded broader relief. The case related to two prescription drugs, Benzedrine (amphetamine sulphate) and Dexedrine (dextroamphetamine sulphate). Plaintiff decided to market these in a new and distinctive heart shape, colored orange for Dexedrine and brown for Benzedrine. Defendant sent postcards to druggists offering to sell the generic drugs in tablets which were exact replicas of plaintiff's; imprinted on the pictorial representations of the tablets was the notation "Color Guaranteed". A later mailing added the words "orange" and "tan". Finding that the shape and color were non-functional and that SKF's advertising had endowed them with secondary meaning, the court entered a temporary injunction restraining defendant from marketing the generic drugs "in tablets having the combination of shape and colors of plaintiff's products or in any other shape and colors so closely resembling the combination of shape and colors of plaintiff's products as to be likely to enable druggists to palm off defendants' products as plaintiff's products."

marketed by Upjohn under differing trade names. There was evidence that two of defendant's salesmen had distributed cards, apparently quite similar to the catalogs in this case, containing a list of defendant's products with a space alongside each on which the names of similar products manufactured by Upjohn had been filled in and had suggested substitution. This court held that such action constituted unfair competition in violation of New York law even though Upjohn had not established secondary meaning and there was no proof of actual substitution. We directed, 246 F.2d at 262, that defendant:

> should be enjoined from either directly or indirectly, representing or suggesting to any one selling any pharmaceutical products similar in contents and appearance to plaintiff's products that such similar products may be substituted for the products of the plaintiff when the latter are prescribed or requested by a physician; and that on the sale of any such products he be required to attach to bottles or containers of a size not made for direct over-the-counter sale, a notice that the contents are not to be sold or dispensed as the product of the plaintiff.

Norwich Pharmacal Co. v. Sterling Drug, Inc., 271 F.2d 569 (2 Cir. 1959), *cert. denied*, 362 U.S. 919 (1960), although heavily relied on by defendants for its statement "[t]hat a color may become someone's exclusive property as a perpetual monopoly in connection with a specific product has been rejected by the courts throughout the years", 271 F.2d at 572, is not of so much assistance to them as they claim. The case dealt with preparations sold in the manufacturers' bottles over-the-counter. The court held that where defendant's product differed in name, container shape and label, copying of the pink color of

plaintiff's liquid was not unfair competition in the absence of proof of secondary meaning or "such practices as constitute palming off, actual deception or appropriation of another's property." 271 F.2d at 571. The court cited *Upjohn Co. v. Schwartz, supra,* as an instance of palming off. *Id.*

This brings us to *Sears* and *Compco, supra,* 376 U.S. 225 and 234. Their precise holding was that a state may not confer protection under its law of unfair competition against the retail sale of articles which were copied from others manufactured under invalid design patents (in *Sears* also under an invalid mechanical patent), simply because of confusion or likelihood of confusion.[9] There is no indication that either Stiffel's lamps or Day-Brite's reflectors were trademarked, although the lamps bore Stiffel tags and the fixtures of which the reflectors were a part were identified by a catalog number. The Sears lamps were sold at retail without identifying tags (although the cartons containing them were marked) and there was some evidence of actual confusion, 376 U.S. at 226-27. On the other hand the Court found "considerable evidence of the care taken by Compco to prevent customer confusion, including clearly labeling both the fixtures and the containers in which they were shipped and not selling through manufacturers' representatives who handled competing lines." 376 U.S. at 237. The holdings clearly apply to goods covered by an expired patent with the same force (or arguably even more, see Brown, Product Simulation, 64 Colum. L. Rev. 1216, 1218-19 (1964)), as to an invalid patent.

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9 In *Compco,* 376 U.S. at 238, the Court accepted the somewhat dubious finding of the trial court "that the configuration of Day- Brite's fixture identified Day-Brite to the trade because the arrangement of the ribbing had, like a trademark, acquired a 'secondary meaning' by which that particular design was associated with Day-Brite."

It has been said that if the lower courts in *Sears* and *Compco* had rested their decisions on "general" principles of unfair competition law rather than on the law of Illinois, the Supreme Court would not have needed more than a citation of *Kellogg* to justify reversal. Brown, Product Simulation, *supra*, at 1216. It was this probably unwarranted reliance, see 376 U.S. at 227 n. 2, that led the Court to take a constitutional ground—preemption by federal patent law—and then to explain how far the preemption extended. The explanation was made in two passages that have been subjected to minute scrutiny:

> Sears has been held liable here for unfair competition because of a finding of likelihood of confusion based only on the fact that Sears' lamp was copied from Stiffel's unpatented lamp and that consequently the two looked exactly alike. Of course there could be "confusion" as to who had manufactured these nearly identical articles. But mere inability of the public to tell two identical articles apart is not enough to support an injunction against copying or an award of damages for copying that which the federal patent laws permit to be copied. Doubtless a State may, in appropriate circumstances, require that goods, whether patented or unpatented, be labeled or that other precautionary steps be taken to prevent customers from being misled as to the source, just as it may protect businesses in the use of their trademarks, labels, or distinctive dress in the packaging of goods so as to prevent others, by imitating such markings, from misleading purchasers as to the source of the goods.[9] But because of the federal patent laws a State may not, when the article is un-

patented and uncopyrighted, prohibit the copying of the article itself or award damages for such copying.

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9 It seems apparent that Illinois has not seen fit to impose liability on sellers who do not label their goods. Neither the discussions in the opinions below nor the briefs before us cite any Illinois statute or decision requiring labeling.

Sears, 376 U.S. at 232-33.

> As we have said in *Sears*, while the federal patent laws prevent a State from prohibiting the copying and selling of unpatented articles, they do not stand in the way of state law, statutory or decisional, which requires those who make and sell copies to take precautions to identify their products as their own. A State of course has power to impose liability upon those who, knowing that the public is relying upon an original manufacturer's reputation for quality and integrity, deceive the public by palming off their copies as the original. That an article copied from an unpatented article could be made in some other way, that the design is "nonfunctional" and not essential to the use of either article, that the configuration of the article copied may have a "secondary meaning" which identifies the maker to the trade, or that there may be "confusion" among purchasers as to which article is which or as to who is the maker, may be relevant evidence in applying a State's law requiring such precautions as labeling; however, and regardless of the copier's motives, neither these facts nor any others can furnish a basis for imposing liability for or prohibiting the actual acts of copying and selling.

Compco, 376 U.S. at 238.

Some, including dissenting Justices, have thought the basic principles of *Sears* and *Compco* were undermined by *Goldstein v. California*, 412 U.S. 546 (1973) (sustaining California law affording state copyright protection for

subject not eligible under the applicable federal copyright law), and *Kewanee Oil Corp. v. Bicron Corp.*, 416 U.S. 470 (1974) (sustaining validity of state trade secret common law). See, e.g., Dannay, The Sears-Compco Doctrine Today; Trademarks and Unfair Competition, 67 Trademark Rep. 132 (1977); The Supreme Court, 1972 Term, 87 Harv. L. Rev. 1, 282 (1973); Zammet, The Ghost of Sears-Compco is Finally Laid to Rest (Or Is It?), 3 Hofstra L. Rev. 37 (1975). However, the majority in both cases disclaimed any intention to depart from *Sears* and *Compco*.

Only a few cases have dealt with the effect of *Sears* and *Compco* on simulation of the color of a trademarked drug. *Marion Laboratories, Inc. v. Michigan Pharmacal Corp.*, 338 F.Supp. 762, 769-70 (E.D. Mich. 1972), aff'd without opinion, 473 F.2d 910 (6 Cir. 1973), assumed that the protection afforded by *Smith, Kline & French Laboratories v. Clark & Clark, supra*, 157 F.2d 725, and *Upjohn Co. v. Schwartz*, 246 F.2d 254, had survived *Sears* and *Compco* but denied relief for inadequacy of proof of either actual or suggested substitution or secondary meaning. In *Merrell-National Laboratories, Inc., v. Zenith Laboratories, Inc.*, 194 U.S.P.Q. 157 (D.N.J. 1977), on facts quite similar to those here, the court issued a preliminary injunction against manufacturers because of "the mere fact that they sold and distributed to the defendant pharmacies and instrumentality of trade which could be passed off as plaintiff's products." Although the Third Circuit affirmed, 579 F.2d 786 (1978), it noted that only after the district court's decision had the manufacturer submitted factual affidavits challenging plaintiff's allegations of unlawful substitution, claiming that these were authorized under New Jersey's generic drug law, and attempting to show a functional basis for the copying; the affirmance was explicitly limited to a holding that the

denial of a motion to redetermine the preliminary injunction on the basis of this new, and contradicted, material was not an abuse of discretion.[10] Quite recently the decision here under review was followed in *Boehringer Ingelheim G. m. b. H. v. Premo Pharmaceutical Laboratories, Inc.*, D.N.J., No. 79-738, decided March 15, 1979, where there was no proof of secondary meaning or illegal substitution.

IV.

Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)[11] goes beyond § 32 in making certain types of unfair competition federal statutory torts, whether or not they involve infringement of a registered trademark. *L'Aiglon Apparel, Inc. v. Lana Lobell, Inc.*, 214 F.2d 649 (3 Cir. 1954); *Federal-Mogul-Bower Bearings, Inc. v. Azoff*, 313 F.2d 405 (6 Cir. 1963). On the other hand, as was said in

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10 Judge Garth, concurring, said that if all the factual material were properly before the court of appeals, he "would have strenuously urged a different disposition on the merits as to the 'palming off' issue" on the basis of *Sears* and *Compco*, 579 F.2d at 792.

11 This reads:

> (a) Any person who shall affix, apply, or annex, or use in connection with any goods or services, or any container or containers for goods, a false designation of origin, or any false description or representation, including words or other symbols tending falsely to describe or represent the same, and shall cause such goods or services to enter into commerce, and any person who shall with knowledge of the falsity of such designation of origin or description or representation cause or procure the same to be transported or used in commerce or deliver the same to any carrier to be transported or used, shall be liable to a civil action by any person doing business in the locality falsely indicated as that of origin or in the region in which said locality is situated, or by any person who believes that he is or is likely to be damaged by the use of any such false description or representation.

an early case under the statute, § 43(a) "should be construed to include only such false descriptions or representations as are of substantially the same economic nature as those which involve infringement or other improper use of trade-marks. It should not be interpreted so as to bring within its scope any kind of undesirable business practice which involves deception, when such practices are outside the field of the trade-mark laws." *Samson Crane Co. v. Union National Sales, Inc.*, 87 F.Supp. 218, 222 (D. Mass. 1949), aff'd per curiam, 180 F.2d 896 (1 Cir. 1950). In this circuit Judge Herlands said much the same in an opinion subsequent to *Sears* and *Compco*, *Geisel v. Poynter Products, Inc.*, 283 F.Supp. 261, 266-68 (S.D.N.Y. 1968). Ives' claim is that, under the circumstances of this case the distinctive color of its capsules is entitled to protection under § 43(a) and that *Sears* and *Compco* were not intended to limit rights accorded by another federal statute.

It is surely true that in the *Sears* and *Compco* opinions the Supreme Court said nothing about the federal tort created by § 43(a).[12] Stiffel's and Day-Brite's claims were treated as resting solely on state unfair competition law which was held invalid as in conflict with federal patent law. The opinions can be read as limited to rights claimed under state unfair competition law granting protection equivalent to that of the federal patent or copyright laws for products not enjoying valid patent or copyright protection. The Court, it can be strongly argued, had no need to be concerned with marking out the boundaries of

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12 This was natural since neither Stiffel nor Day-Brite made any claim under § 43(a). The Lanham Act was cited to the Supreme Court only by the Government's *amicus* brief in a *cf.* type of reference to the refusal to grant trademark registration to functional configurations in *Application of Diester Concentrator Co.*, 289 F.2d 496 (CCPA 1961).

a federal tort over which it had complete control and which Congress could contract if the courts were pressing it further than that body desired.[13] The Eighth Circuit took essentially this position in *Truck Equipment Service Co. v. Fruehauf Corp.*, 536 F.2d 1210, 1214-15, *cert. denied*, 429 U.S. 861 (1976). The court there sustained a claim under § 43(a) for copying the exterior design of a hopper grain trailer which was found to be nonfunctional and to have acquired a secondary meaning.[14] While we previously left this question open in *Bose Corp. v. Linear Design Labs, Inc.*, 467 F.2d 304, 309-10 (1972), we are now prepared to agree with the Eighth Circuit.

Assuming that the law developed by federal courts under § 43(a) prior to *Sears* and *Compco* continues to govern and that the precise strictures there addressed to

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13 A contrary argument could be constructed on the basis that Art. I, § 8, authorizes Congress to secure "to authors and inventors the exclusive right to their respective writings and discoveries" only "for limited times." See Bender, Product Simulation, 64 Colum. L. Rev. 1228, 1230 (1964). However, nothing in the *Sears* and *Compco* opinions suggests that the Court was aiming shafts at Congress, and it would be hard to argue that the time limitation on the power of Congress to protect "writings and discoveries" limits its power under the commerce clause to protect trademarks or other symbols of origin. A commentator has categorically declared that "*Sears-Compco* do not affect rights under other federal statutes." Dannay, The Sears-Compco Doctrine Today: Trademarks and Unfair Competition, 67 Trademark Reporter 132, 143 (1977).

14 After quoting the passage from *Compco* which we have quoted above, the court characterized the Supreme Court's language as dictum, 536 F.2d at 1214. We would say rather that it did not purport to be addressed to rights recognized by § 43(a) of the Lanham Act.

It is of interest that, as noted in Comment, Product Simulation in the Eighth Circuit, 57 Neb. L. Rev. 91 (1978), the trial court eventually decided that, because of the extensive sales by Fruehauf, the shape was not identified with plaintiff as source, and modified the injunction merely to prohibit the deceptive advertising and to require labeling.

the states may not be applicable to a claim under that section, this still leaves the question whether Ives showed a probability of success or a fair ground for litigation and a balance of hardships tipping decidedly in its favor. A good statement of the law under § 43(a) is in *Pagliero v. Wallace China Co.*, 198 F.2d 339, 343 (9 Cir. 1952), quoted in *Bliss v. Gotham Industries, Inc.*, 316 F.2d 848, 855 (9 Cir. 1963), on which the Eighth Circuit relied in the *Truck Equipment* case:

> Imitation of the physical details and designs of a competitor's product may be actionable, if the particular features imitated are 'non-functional' and have acquired a secondary meaning. Crescent Tool Co. v. Kilborn & Bishop Co., 2 Cir., 1917, 247 F. 299. But, where the features are 'functional' there is normally no right to relief. 'Functional' in this sense might be said to connote other than a trade-mark purpose. If the particular feature is an important ingredient in the commercial success of the product, the interest in free competition permits its imitation in the absence of a patent or copyright. On the other hand, where the feature or, more aptly, design, is a mere arbitrary embellishment, a form of dress for the goods primarily adopted for purposes of identification and individuality and, hence, unrelated to basic consumer demands in connection with the product, imitation may be forbidden where the requisite showing of secondary meaning is made. Under such circumstances, since effective competition may be undertaken without imitation, the law grants protection.

One would not initially suppose the color of a capsule to be functional. Unlike the chocolate in the *Warner* case, *supra*, the blue and blue-and-red coatings of Ives' capsules

do not contribute to their efficacy; any other colors would do as well.[15] The argument that, like functional elements, color ought to be automatically denied protection because of the risk of creating monopolies through tying up all available colors, cf. *Morrissey v. Proctor & Gamble Co.*, 379 F.2d 675 (1 Cir. 1967), does not seem persuasive; the evidence showed that, in addition to the other primary colors, an endless number of color combinations was available to the defendants. The case for functionality thus depends on the evidence proffered by defendants that copying whatever colors Ives had chosen served a number of utilitarian purposes, see 455 F.Supp. at 949-50, essential to effective competition. At this stage of the case we need not go beyond saying that the judge was warranted in considering this to be fairly arguable.

With respect to secondary meaning we cannot say that Ives would necessarily be unable to establish that consumers had come to associate the blue and blue-and-red colors with the trademark Cyclospasmol. Mr. Justice Holmes said long ago, *American Waltham Watch Co. v. United States Watch Co.*, 173 Mass. 85, 87 (1899):

> It is true that a man cannot appropriate a geographical name, but neither can he a color, or any part of the English language, or even a proper name to the exclusion of others whose names are like his. Yet a color in connection with a sufficiently complex combination of other things may be recognized as saying so circumstantially that the defendant's goods are the plaintiff's as to pass the injunction line.

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15 While color was held to be functional in *Smith, Kline & French Labs v. Clark & Clark, supra*, 157 F.2d at 730, this was because white was the natural color of the tablets and there would be some extra cost in coating them. Here the defendants must place the powder in a capsule and one color is no more expensive than another.

It is significant that, given the method of sale, Ives had no way of identifying Cyclospasmol to the ultimate consumer other than by the color of the capsule and by the imprint on it, which is contended to be of dubious value. See Note, Unfair Competition and the Doctrine of Functionality, 64 Colum. L. Rev. 544, 557-58 and nn. 93 & 94 (1964). This distinguishes the case from *Norwich Pharmacal Co. v. Sterling Drug, Inc., supra,* 271 F.2d 569, where differences in name, labelling and packaging seen by the consumer were such that the court thought "it stretches credulity to imagine a purchaser confusing these disparate articles." 271 F.2d at 571. Also the fact that the association was due to Ives' having been the exclusive source of cyclandelate during the patent period does not deprive Ives of an opportunity to show that a non-functional configuration or trade dress had developed secondary meaning, see, e.g., *Mine Safety Appliances Co. v. Electric Storage Battery Co.,* 405 F.2d 901, 902 n. 2 (CCPA 1969); *Application of Mogen David Wine Corp.,* 328 F.2d 925 (CCPA 1964) and 372 F.2d 539 (CCPA 1967), and we see no basis in principle for saying that simply because the colored capsule is ingested, the color cannot constitute "trade dress". However, plaintiff "agreed not to rely on secondary meaning for purposes of the motion except to argue that defendants' copying in itself constitutes 'evidence' of secondary meaning," 455 F.Supp at 950.

We find rather less merit in plaintiff's claims under New York law than in those under § 43(a) of the Lanham Act. It is true that we have recognized the breadth of the relief which New York affords against unfair competition, *Flexitized Inc. v. National Flexitized Corp.,* 335 F.2d 774, 781-82 (1964), *cert. denied* 380 U.S. 913 (1965), and there took a rather limited view of the extent to which

the then recent *Sears* decision had interfered with this, 335 F.2d at 781 n. 4. Apart from the question whether the *Flexitized* footnote adequately recognized the blow dealt by *Sears* and *Compco* to state unfair competition laws, "New York law" now includes its generic drug law, Education Law §§ 6810-6826, and we do not know how New York will strike the balance between unfair competition claims of manufacturers of branded drugs and the policy of generic drug laws facilitating substitution when the physician has authorized this. On this aspect of the case, defendants' claims that patients would be put off in accepting substitution by a change from the familiar colors, if factually established, see Swenson, Property Rights in the Color and Shapes of Capsules, 32 Food Drug & Cosm. L. J. 361, 367-68 (1977),[16] would be especially pertinent. Whether plaintiff would be entitled to relief under the unfair competition law of other states, particularly those without generic drug laws, is not before us.

The upshot of our consideration is that while we are not so convinced that *Sears* and *Compco* are an insurmountable barrier to plaintiff as was the district judge and, indeed, believe them to have only tangential bearing on the Lanham Act claims, this is an appropriate case for applying the "rule" that denial of a temporary injunction should not be reversed save for "abuse" of discretion. *State of New York v. Nuclear Regulatory Commission*, 550 F.2d 745, 750-53 (2 Cir. 1977) and cases there cited. Although some depositions were taken, the motion was heard largely on affidavits. As noted above, the evidence of improper substitution was limited to 15 prescriptions.[17]

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16 Mr. Swenson is trademark counsel to Eli Lilly & Co.

17 In 12 instances the product was labeled as Cyclospasmol.

Discovery and trial might show that the practice was much more widespread or, on the other hand, as defendants suggest, that the pharmacies in question were known bad actors and few others engaged in such practices. Although plaintiff doubtless made the required minimal showing of "irreparable injury", namely, that if it is entitled to a final injunction, its interim damages cannot be calculated with sufficient accuracy to make damages an adequate substitute, see *Buffalo Courier-Express Inc. v. Buffalo Evening News, Inc.*, No. 77-7617, decided April 16, 1979, slip opinions 2183, 2203-04 (2 Cir.), there is no showing that its business will be seriously imperiled in the interval before a decision can be rendered after a trial; on the other hand, the issuance of a preliminary injunction would clearly have wreaked serious harm on the defendants. In sum, we cannot say that Ives sufficiently demonstrated probability of success for the broad injunction that it demanded and, while it did tender issues affording a fair ground for litigation, the balance of hardships did not tip decidedly in its favor, see note 4, *supra*.

The order is therefore affirmed. After trial the district court will, of course, consider whether even if under our analysis Ives is not entitled to the full relief demanded, it should not be awarded more limited relief of the sort granted in *Warner, Kellogg* and other cases.

APPENDIX C — OPINION OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK, *IVES LABORATORIES, INC. v. DARBY DRUG CO., INC.*, 488 F. SUPP. 394 (E.D.N.Y. 1980)

United States District Court
E.D. New York

No. 78 C 372

April 15, 1980

IVES LABORATORIES, INC.,

Plaintiff,

v.

DARBY DRUG CO., INC., Inwood Laboratories Incorporated, MD Pharmaceutical Company, Inc., Premo Pharmaceutical Company, Inc., Rugby Laboratories, Inc., and Sherry Laboratories Co., Inc.,

Defendants.

First drug manufacturer brought action against drug wholesalers and other manufacturers for alleged contributory infringement and false designation of origin in violation of Lanham Act, as well as violation of New York Unfair Competition Law, in connection with marketing of cyclandelate. The United States District Court for the Eastern District of New York, Eugene H. Nickerson, J., 455 F. Supp. 939, entered order denying motion for preliminary injunction, and appeal was taken. The Court of Appeals, 601 F.2d 631, affirmed. Following trial to court, the District Court, Nickerson, J., held that: (1) evidence established that defendants did not suggest, even by implication, that pharmacists fill bottles with generic drug

cyclandelate and apply first manufacturer's trademark, "Cyclospasmol," and evidence did not establish that defendants continued to sell the generic drug to pharmacists whom defendants knew or had reason to know were engaging in such practice, and thus evidence failed to establish contributory infringement, and (2) evidence established that use by all manufacturers and wholesalers of blue and blue and red colors for pills was functional, and first manufacturer failed to establish that such colors indicated sponsorship or origin, and thus first manufacturer failed to establish that the colors had acquired secondary meaning so as to justify it having monopoly over use of such colors.

Complaint dismissed except for judgment permanently enjoining party from using word "Spasmol" in marketing the drug.

* * *

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Bass, Ullman & Lustigman, New York City (Steven R. Trost, New York City, of counsel), for defendant Inwood.

Appendix C

MEMORANDUM AND ORDER

NICKERSON, District Judge.

Plaintiff Ives Laboratories, Inc. ("Ives"), which makes and sells the prescription drug cyclandelate under the registered trademark Cyclospasmol, brought this action seeking an injunction against defendants, manufacturers or wholesalers of generic cyclandelate. Ives claims violations of the Trademark Act of 1946, as amended, (the "Lanham Act"), 15 U.S.C. §§1051ff., and of New York statutory and common law. The court has jurisdiction pursuant to 28 U.S.C. §§1331 and 1338.

On Ives' motion for a preliminary injunction this court temporarily enjoined defendant Sherry Pharmaceutical Co., Inc. ("Sherry") from using the name Spasmol, but otherwise denied Ives temporary relief, 455 F. Supp. 939 (D.C.N.Y. 1978), and the Court of Appeals affirmed, 601 F.2d 631 (2d Cir. 1979). The case was then tried to the court. Familiarity with the prior opinions is assumed.

I

The drug cyclandelate, a white powder, is a peripheral vasodilator claimed to produce an increase in blood flow and thereby inhibit the progressive conditions caused by certain vascular diseases which tend to occur in the aged. Cyclandelate is therefore prescribed for a long period of time, generally for the rest of the patient's life. For some years Ives, its predecessors and its parent company American Home Products Corporation have sold the drug under the mark Cyclospasmol, and until the patent on cyclandelate expired in April 26, 1972, had the exclusive right to make and sell the drug in the United States.

Ives has been marketing 200 mg. dosages in a pale blue capsule imprinted "Ives 4124" since 1962, and 400 mg. dosages in a red and blue capsule imprinted "Ives 4148" since 1975.

Because the drug may be dispensed only on prescription, Ives has directed its considerable advertising and promotion not to the general public but primarily to physicians. Some two hundred and thirty so-called "detail" men have made personal visits to doctors distributing numerous samples and various promotional materials. Advertising and promotional expenses have been in excess of $10,000,000. Ives' sales of the drug since 1962 have exceeded $106,000,000.

Of the defendants remaining in the case three are manufacturers, namely, Premo Pharmaceutical Laboratories, Inc. ("Premo"), Inwood Laboratories, Incorporated ("Inwood"), and MD Pharmaceutical Company, Inc. ("MD") (collectively "the manufacturers"). All three purchase cyclandelate powder and empty capsules and assemble the product for sale to wholesalers and hospitals. Inwood and MD also sell to retail pharmacies. Premo and Inwood sell 200 mg. and 400 mg. capsules in colors identical to those used by Ives. MD does the same with 200 mg. capsules. Since the action was brought, Premo has imprinted the word Premo on its capsules and Inwood has imprinted "NDC 258" on its capsules. MD sells capsules bearing no imprint. Defendants Darby Drug Co., Inc. ("Darby"), Rugby Laboratories, Inc. ("Rugby"), and Sherry (collectively "the wholesalers") purchase capsules of the kind made by the manufacturers and sell them primarily to physicians and pharmacies.

All the defendants promote the generic product as "comparable" or "similar" or "equivalent" to Cyclospasmol, and

in some catalogs refer to the color of the capsules. Defendants' cyclandelate contains the same active ingredient as Cyclospasmol, and Ives offered no proof at the trial that defendants' product had a therapeutic effect different from that of Cyclospasmol.

Sherry had offered the drug under the name Spasmol, but abandoned that name prior to the motion for a preliminary injunction. The remaining defendants do not sell under a brand name.

Ives sells to druggists and wholesalers in packages identifying its name and displaying the trademark Cyclospasmol. Pharmacists then dispense the capsules in smaller bottles with their own labels. In New York State the New York Drug Substitution Law spells out the pharmacist's duty. Section 6810(6) of the Education Law requires the prescription form to recite that it will be filled generically unless the doctor signs over the line stating "dispense as written". The other line which must appear on the form reads "substitution permissible". If the doctor signs over that line, Section 6816-a(i) requires the druggist to "substitute a less expensive drug" having the same active ingredients provided it appears on a list established under the New York Health Law. If the drug is not on the list, as cyclandelate is not, the druggist may but need not substitute the less expensive drug.

Unless the physician otherwise directs, the pharmacist must include on the label the strength of the drug and its brand name, if it has one, or, if it is sold under the generic name, that name and the name of the manufacturer. Thus, for example, if dispensing a 200 mg. dosage of Ives' product the pharmacist should state on the label, "Cyclospasmol 200 mg.", or, if dispensing Premo's product, "Cyclandelate 200 mg. Premo".

Appendix C

Ives' chief objective in this action is to prohibit defendants from marketing cyclandelate in capsules of the same blue and blue and red colors as Ives uses.

II

There is no reason why the temporary injunction against Sherry prohibiting use of the name "Spasmol" should not be made permanent.

III

Ives' claim that defendants are guilty of contributory infringement under Section 32 of the Lanham Act, 15 U.S.C. §1114, was not proven. The court finds that defendants did not suggest, even by implication, that pharmacists fill bottles with the generic drug cyclandelate and apply the trademark Cyclospasmol. Nor did Ives show that defendants continued to sell the generic drug to pharmacists who defendants knew or had reason to know were engaging in such a practice. 601 F.2d at 636.

Defendants do not "detail" their products by making personal visits to pharmacists, and defendants' names appear on their packages of cyclandelate capsules. Therefore any suggestion by defendants that pharmacists mislabel must be found in defendants' catalogs and promotional materials. These materials cannot fairly be read as suggesting to druggists that they affix Ives' mark to bottles containing defendants' capsules.

Moreover, such incidents of mislabeling as were proven were not shown to have been induced by defendants. There was no proof of illegal substitution accompanied by mislabeling beyond the few instances referred to on the motion for a

preliminary injunction. Ives did offer evidence at trial of a few instances of legal substitution where the word Cyclospasmol was improperly used on the label. Some Ives test shoppers gave a prescription for Cyclospasmol signed on the line over "substitution permissible" to forty-two pharmacists in New York selected from a list supplied by Ives and forty-one from a list of drug stores in Hayes Directory. Of the forty-two on the Ives list twenty-four dispensed Cyclospasmol, and eighteen dispensed the generic product. Six of those eighteen included the word Cyclospasmol on the label. Of the forty-one on the Hayes Directory list twenty-four dispensed Cyclospasmol and seventeen dispensed the generic product. Four of those seventeen included the word Cyclospasmol on the label.

Of the total of ten pharmacists who dispensed generic cyclandelate and also used the word Cyclospasmol on the label, four used the term "generic Cyclospasmol" or "Cyclospasmol generic" and one the term "Cyclospasmol Gen." Nine of the ten informed the person buying the capsules that the generic product had been dispensed. Only one appears to have charged a higher "brand" price. This evidence hardly justifies an inference that defendants' catalogs impliedly invited druggists to mislabel.

To the extent the druggists who were test shopped by Ives mislabeled they appear not deliberately to have been attempting to pass off the generic product as Cyclospasmol but rather to have misunderstood the precise requirements of the New York Drug Substitution Law. Indeed, the misunderstanding of the law is confirmed by the numerous instances in which pharmacists dispensed Cyclospasmol and, although a generic substitution was permitted by the prescription, erroneously stated to the person presenting the prescription that New York law prohibited them from filling it with a generic product.

Appendix C

In accordance with the direction of the Court of Appeals this court has considered whether Ives should have limited relief of the sort mentioned in *William R. Warner & Co. v. Eli Lilly & Co.*, 265 U.S. 526, 532-33, 44 S. Ct. 615, 618, 68 L. Ed. 1161 (1924). The Court has concluded that it would not be useful to require defendants to recite on their packages that the product is not to be dispensed as Cyclospasmol. Defendants' packages do not represent that they contain Cyclospasmol, and the evidence shows that druggists are well aware of the difference between the brand and the generic product. As noted above, any mislabeling stemmed from doubt as to the requirements of the generic drug law, not from inducement by defendants. Statements on defendants' packages are hardly likely to deter those isolated instances of deliberate and fraudulent substitution by pharmacists. Perhaps recourse to the civil and criminal penalties available will do so.

Nor would it be fruitful to require all defendants to print their names on the capsules. The evidence showed that the capsules are so small that such an imprint would be of little if any value.

The court holds that plaintiff is not entitled to relief against defendants for contributory infringement of the trademark Cyclospasmol.

IV

Ives' chief claim is that defendants are violating Section 43(a) of the Lanham Act, 15 U.S.C. §1125(a). That section provides, in pertinent part, that one who uses in connection with goods "a false designation of origin, or any false description or representation, including words or other symbols tending falsely

to describe or represent" the goods shall be liable in a civil action to "any person who believes that he is or is likely to be damaged by the use of any such false description or representation."

Ives contends first that it was "false" for defendants to promote their product as "comparable" or "equivalent" to Cyclospasmol. This claim was not proven. Indeed, Ives offered no evidence on the point and admitted that defendants' product has the same active ingredient as Cyclospasmol.

Ives' most serious contention is that defendants' use of the blue and blue and red colors is "a false designation of origin" or a "false description or representation" of defendants' product and that Ives should therefore have the exclusive use of those colors in selling cyclandelate. This court must follow the Court of Appeals' holding, 601 F.2d at 639-42, as to *Sears, Roebuck & Co. v. Stiffel Company*, 376 U.S. 225, 84 S. Ct. 784, 11 L. Ed. 2d 661 (1964) and *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234, 84 S. Ct. 779, 11 L. Ed. 2d 669 (1964), and accordingly considers whether or not the colors are "functional" and, if they are not, whether they have acquired a "secondary meaning" so as to justify Ives having a monopoly over them.

The Court of Appeals quoted, 601 F. 2d at 642-43, as a "good statement of the law" an excerpt from *Pagliero v. Wallace China Co.*, 198 F.2d 339, 343 (9th Cir. 1952). That quotation recites that the word "functional" connotes other than a trademark purpose and that "[i]f the particular feature is an important ingredient in the commercial success of the product, the interest in free competition permits its imitation in the absence of a patent or copyright."

Appendix C

The court finds that the colors are functional in several respects. First, many elderly patients associate the appearance of their medication with its therapeutic effect. There was testimony that some patients refuse to take equivalent drugs of a different color despite explanation of the equivalence by their doctors. Other patients eventually accept equivalent drugs of a different appearance if their physician assures them that the prescription was filled correctly but are caused considerable anxiety and confusion by the change. When patients associate the drug with its therapeutic effect in this manner, to insist that defendants use a different color would unjustifiably put them at a competitive disadvantage. Thus color is an important ingredient in the commercial success of the product.

Second, some patients co-mingle their drugs in a single container and then rely on the appearance of the drug to follow their doctors' instructions. One doctor testified that he prepared a chart using the color and shape of the medication to help disoriented and forgetful patients avoid confusion between several drugs. While this practice is not universal, clearly some doctors use the appearance of a drug in communicating with their patients and in assisting them to take the correct medications at the appropriate times.

Third, to some limited extent color is also useful to doctors and hospital emergency rooms in identifying overdoses of drugs. There was testimony that the color of a capsule provides one clue in an often difficult and hurried effort to determine what a patient has ingested.

The functional aspect of the color of the capsules is further evidenced by the fact that the parent of Inwood discontinued sale of cyclandelate in a green capsule because the different color was not accepted by hospitals, pharmacies and wholesalers in

the light of the potential for confusion. One hospital official testified that he refused to purchase cyclandelate in a green capsule.

A different situation would be presented if wholesalers, pharmacies and hospitals insisted on purchasing generic cyclandelate in colors identical to those of Ives so that they could unlawfully pass off the generic product as that of Ives. But nothing in the record suggests such a motive. The fact is that, not surprisingly, the colors have come to represent to large numbers of those taking cyclandelate not its source but its ingredients and their effects. The colors are thus functional to the patients as well as to doctors and hospitals.

But even if the colors are not functional in the sense intended by the Court of Appeals, Ives failed to show that the colors indicate sponsorship or origin and have therefore acquired a secondary meaning.

To establish secondary meaning a plaintiff "must show that the primary significance of the term in the minds of the consuming public is not the product but the producer." *Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111, 118, 59 S. Ct. 109, 113, 83 L. Ed. 73 (1938). As the Court of Appeals indicated, 601 F. 2d at 643, in quoting from *Waltham Watch Co. v. United States Watch Co.*, 173 Mass. 85, 87, 53 N.E. 141, 142 (1899) (Holmes, J.), "a color in connection with a sufficiently complex combination of other things may be recognized as saying so circumstantially that the defendant's goods are the plaintiff's as to pass the injunctive line." *See also Dallas Cowboys Cheerleaders, Inc. v. Pussycat Cinema, Ltd.*, 604 F.2d 200, 203-204 (2d Cir. 1979). But the colors must "say" that "the defendant's goods are the plaintiff's," in other words, must convey the message not merely that the goods have the same

active ingredients and effect but that they are in fact the plaintiff's goods. In short, in order to establish secondary meaning Ives must demonstrate that patients suppose that the blue and blue and red colors indicate the source, albeit the anonymous source, of the drug and not its chemical ingredients or its function.

Doctors are, of course, well aware that generic and brand name drugs come from different sources. Ives did not contend that in deciding on a prescription doctors were confused by the identical colors. Rather Ives sought to establish that the colors had a secondary meaning to the patient.

Ives failed to do this. The doctors who testified believed that patients do not associate the appearance of a drug capsule with the manufacturer or other source but with the drug's effect on the patient's disability. Patients tend to identify capsule colors with their ailments, for example, "my red heart pill". Ives made no showing that any patient took the colors to mean that the drug came from a particular source.

Ives offered testimony as to a survey said to be relevant to secondary meaning. Those taking the survey refused to reveal the identity of the actual interviewers or those interviewed. There was thus no way in which the defendants could test the trustworthiness of the results. For this reason the court would in any event accord the survey very little weight. But even assuming that the survey's techniques were sound (as to which the court does not express an opinion), the survey did not constitute proof that the colors had acquired a secondary meaning.

Thirty-six patients who were taking the blue or blue and red Cyclospasmol capsules were interviewed. Of the thirty-six, one third were not even aware that Cyclospasmol had been

prescribed for them. Of the other twenty-four, only twelve spontaneously identified the blue or blue and red generic capsules as Cyclospasmol. The remaining twelve who did not at first say the capsules were then given a card listing ten names of drugs including Cyclospasmol (but not cyclandelate), and finally identified the capsules as Cyclospasmol.

The court finds significant not how many patients named Cyclospasmol but how few did. All of them had been prescribed the Cyclospasmol brand. All of them took only that brand. The survey did not indicate that any of them had ever heard any other name for the drug. Yet only twelve people, a third of the entire sample, could without prompting associate the word Cyclospasmol with capsules of colors identical to those of Ives. Moreover, as to those twelve there was no evidence that they supposed that Cyclospasmol was a brand name or indicated the source of the drug.

Ives argues that because "Cyclospasmol" is a trademark which only it can use, a patient who identifies a cyclandelate capsule as "Cyclospasmol" is necessarily indicating that he believes the drug comes from a single source. But even as to the trademark itself we must "remember that relief always depends upon the idea that no man shall be allowed to mislead people into supposing that his goods are the plaintiff's, and that there can be no right or remedy until plaintiff can show that at least presumptively this will result." *Bayer Co. v. United Drug Co.*, 272 F. 505, 509-510 (S.D.N.Y. 1921) (L. Hand, J.).

No doubt to physicians and pharmacists the word "Cyclospasmol" signifies a source. But there is no reason to suppose this is so as to patients. They have not been the target of the sales campaigns, and they play no role in choosing what drug to buy. Nothing in the record suggests that they

"understand by the word anything more than a kind of drug to which for one reason or another they [have] become habituated." *Id.* at 510. Such patients as read their prescriptions do not attribute to Cyclospasmol "any other meaning than as an ingredient in a general compound, to which faith and science might impart therapeutic virtue." *Id.*

Thus, one cannot infer from the fact that patients recognize the name Cyclospasmol that they appreciate that the drug they receive comes from a single source. If they do not know that the word designates a single source, it follows that a color they associate with the name does not signify to them a single source and cannot acquire a secondary meaning.

No doubt one can imagine circumstances under which a patient believes the word Cyclospasmol to be a brand name and therefore associates the colors with one source. For example, a doctor or druggist might explain to the patient that Cyclospasmol is one brand of cyclandelate. For that patient the blue and blue and red colors may perhaps attain a secondary meaning. But Ives did not offer proof that any patient received some such explanation from a physician or a pharmacist. More importantly, no question in the survey was designed to show whether patients supposed that Cyclospasmol emanated from a single, although unidentified, source.

Ives claims that the interest of patients in receiving the very drug prescribed by their doctor will not be adequately protected unless Ives has a monopoly over the colors. Implicit in this argument is the contention that even if Ives cannot show secondary meaning it is entitled to exclusive use of its capsule colors because there is no other way to identify its product to its ultimate consumers. However, the Lanham Act does not purport to confer "property rights", but, as noted, only to prohibit a

"false description or representation" of a product. Since Ives did not show that the blue and blue and red capsule colors had acquired a secondary meaning, there was no "false description or representation".

For this reason, the fact that defendants intentionally duplicated the blue and blue and red colors does not prove the existence of secondary meaning. Unless the colors bespeak the source of the capsules, defendants have every right to imitate them. As Justice Brandeis said in *Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111, 122, 59 S. Ct. 109, 115, 83 L. Ed. 73 (1938), "Sharing in the goodwill of an article unprotected by patent or trade-mark is the exercise of a right possessed by all—and in the free exercise of which the consuming public is deeply interested."

Ives' failure of proof highlights the difficulty of proving secondary meaning to consumers in the prescription drug market. In urging that Section 43(a) of the Lanham Act be read to grant Ives a perpetual monopoly over the blue and blue and red colors, Ives cites cases involving both prescription drugs and ordinary goods sold over the counter. But decisions concerning goods which the seller promotes directly to the consumer cannot indiscriminately be used as authority in a case concerning prescription drugs. Where the advertising and promotion are aimed at the customers who make the choice of which product to buy, they may indeed take a non-functional feature to indicate not merely the product but also the producer. In that case, vast expenditures for advertising may suggest that the advertising was successful in implanting in the minds of the consumer the idea that certain features by which the product is promoted identify its source. But extensive promotion to physicians does not establish that they have passed along to their patients any message as to source. For that reason secondary

meaning will perhaps be difficult to establish in those prescription drug cases where the patient never sees the manufacturer's packaging. Here Ives certainly did not establish secondary meaning.

The court concludes that Ives has not made out a violation of Section 43(a) of the Lanham Act.

V

Little need be added to the discussion in the prior opinions of Ives' claims under New York law. *See* 455 F. Supp. at 951; 601 F. 2d at 644. Ives contends primarily that whether or not the blue and blue and red colors have acquired a secondary meaning and thus constitute a false representation, the New York law of unfair competition should be construed to protect patients by making it easy for them to detect instances in which the pharmacist has made an improper substitution of the generic for the brand name drug.

Assuming that this contention is not foreclosed by *Sears, Roebuck & Co. v. Stiffel Company*, 376 U.S. 225, 84 S. Ct. 784, 11 L. Ed. 2d 661 (1964) and *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234, 87 S. Ct. 779, 11 L. Ed. 2d 669 (1964), this interest of the patients must be weighed against the policy expressed in the New York Education Law to encourage legal substitution of lower priced drugs. One of Ives' witnesses testified that improper substitution is rare, and Ives showed only a few instances of it. This infrequency may be explained in part by the fact that illegal substitution is subject to both civil and criminal penalties under New York law. To require different capsule colors might to some small extent deter a wrongdoer but it would also severely inhibit legal substitution which the legislature deems to be in the public interest. When the

competitive injury which as injunction would cause to defendants is added to the balance, the patients' ease in detecting a potential improper substitution is outweighed by the interest in fostering the use of generic substitutes.

VI

The foregoing constitutes the court's findings of fact and conclusions of law. Plaintiff may have judgment permanently enjoining Sherry from using the word "Spasmol". Otherwise the complaint is dismissed. So ordered.

APPENDIX D — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT, *IVES LABORATORIES, INC. v. DARBY DRUG CO., INC.*, 638 F. 2d 538 (2D CIR. 1981)

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

No. 150—September Term, 1980

(Argued September 5, 1980 Decided January 8, 1981)

Docket No. 80-7314

IVES LABORATORIES, INC.,

Plaintiff-Appellant,

—against—

DARBY DRUG CO., INWOOD LABORATORIES INCORPORATED, MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,

Defendants-Appellees.

Before:

LUMBARD, MANSFIELD and MULLIGAN,

Circuit Judges.

Appendix D

Appeal from a judgment of the District Court for the Eastern District of New York entered by Judge Eugene H. Nickerson, after a non-jury trial, dismissing plaintiff's suit against defendants for violation of §§ 32 and 43(a) of the Lanham Act, 15 U.S.C. §§ 1114 and 1125(a), and New York State unfair competition laws.

Reversed and remanded.

MARIE V. DRISCOLL, Esq., New York, NY (David C. Stimson, Esq., Egon E. Berg, Esq., Steven Baron, Esq., Rogers Hoge & Hills, New York, NY, of counsel), *for Appellant.*

PETER T. COBRIN, Esq., New York, NY (Martin W. Schiffmiller, Esq., Kirschstein, Kirschstein, Ottinger & Cobrin, New York, NY, of counsel), *for Appellee Premo Pharmaceutical Laboratories, Inc.*

STEVEN R. TROST, Esq., New York, NY (Bass, Ullman & Lustigman, New York, NY, of counsel), *for Appellee Inwood Laboratories Incorporated.*

ROBERT V. MARROW, Esq., New York, NY (Salon, Marrow & Dyckman, New York, NY, of counsel), *for Appellees Darby Drug Co, MD Pharmaceutical Company, Inc., and Sherry Pharmaceutical Co., Inc.*

Appendix D

MANSFIELD, *Circuit Judge*:

Ives Laboratories, Inc. ("Ives") brought suit in the District Court for the Eastern District of New York against appellees, who are drug manufacturers and wholesalers, claiming that their manufacture and distribution of a generic drug using capsules identical in color, shape, and size to those long used by Ives in its equivalent trademarked product violated §§ 32 and 43(a) of the Lanham Act, 15 U.S.C. §§ 1114 and 1125(a), and New York State unfair competition laws.[1] The district court,

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1 Title 15 U.S.C. § 1114 reads as follows:

"§ 1114. *Remedies; infringement; innocent infringement by printers and publishers*

(1) Any person who shall, without the consent of the registrant—

(a) use in commerce any reproduction, counterfeit, copy, or colorable imitation of a registered mark in connection with the sale, offering for sale, distribution, or advertising of any goods or services on or in connection with which such use is likely to cause confusion, or to cause mistake, or to deceive; or

(b) reproduce, counterfeit, copy, or colorably imitate a registered mark and apply such reproduction, counterfeit, copy, or colorable imitation to labels, signs, prints, packages, wrappers, receptacles or advertisements intended to be used in commerce upon or in connection with the sale, offering for sale, distribution, or advertising of goods or services on or in connection with which such use is likely to cause confusion, or to cause mistake, or to deceive,

shall be liable in a civil action by the registrant for the remedies hereinafter provided. Under subsection (b) of this section, the registrant shall not be entitled to recover profits or damages unless the acts have been committed with knowledge that such imitation is intended to be used to cause confusion, or to cause mistake, or to deceive.

(2) Notwithstanding any other provision of this chapter, the remedies given to the owner of the right infringed shall be limited as follows: (a) Where an infringer is engaged solely in the business of printing the mark for others and establishes that he was an innocent infringer the owner of the right infringed shall be entitled as against such infringer only to an injunction against future printing; (b) where the infringement complained of is contained in or is part of paid advertising matter in a newspaper, magazine, or other similar

Nickerson, J., denied Ives' motion for a preliminary injunction, 455 F. Supp. 939. Upon appeal we affirmed, noting that "we find the case more difficult than did the district judge." 601 F.2d 631, 634. On remand the district court, after a bench trial, found for the appellees.[2] 488 F. Supp. 394. We reverse on the ground that the undisputed

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periodical the remedies of the owner of the right infringed as against the publisher or distributor of such newspaper, magazine, or other similar periodical shall be confined to an injunction against the presentation of such advertising matter in future issues of such newspapers, magazines, or other similar periodical: *Provided*, That these limitations shall apply only to innocent infringers; (c) injunction relief shall not be available to the owner of the right infringed in respect of an issue of a newspaper, magazine, or other similar periodical containing infringing matter when restraining the dissemination of such infringing matter in any particular issue of such periodical would delay the delivery of such issue after the regular time therefor, and such delay would be due to the method by which publication and distribution of such periodical is customarily conducted in accordance with sound business practice, and not to any method or device adopted for the evasion of this section or to prevent or delay the issuance of an injunction or restraining order with respect to such infringing matter."

Title 15 U.S.C. § 1125(a) provides:

"§ 1125. *False designations of origin and false descriptions forbidden*

"(a) Any person who shall affix, apply, or annex, or use in connection with any goods or services, or any container or containers for goods, a false designation of origin, or any false description or representation, including words or other symbols tending falsely to describe or represent the same, and shall cause such goods or services to enter into commerce, and any person who shall with knowledge of the falsity of such designation of origin or description or representation cause or procure the same to be transported or used in commerce or deliver the same to any carrier to be transported or used, shall be liable to a civil action by any person doing business in the locality falsely indicated as that of origin or in the region in which said locality is situated, or by any person who believes that he is or is likely to be damaged by the use of any false description or representation."

2 The only part of plaintiff's complaint which the district court did not dismiss after trial was Ives' request for a judgment permanently enjoining defendant Sherry Pharmaceutical Co., Inc., from using the word "Spasmol" in marketing cyclandelate.

evidence establishes a violation of § 32 and remand for further proceedings not inconsistent with this opinion.[3] In view of our holding in favor of Ives on the § 32 issue we express no views on the other issues raised by it on this appeal.

Ives has for some years manufactured a prescription drug called CYCLOSPASMOL. CYCLOSPASMOL is a peripheral vasodilator designed to produce an increase in blood flow; it is most commonly prescribed for ingestion by elderly patients who are experiencing progressive circulatory difficulties. Until 1972 Ives held a patent on CYCLOSPASMOL. Since that time it has continued to hold a trademark to the name CYCLOSPASMOL, but several generic drug manufacturers (including some of the appellees) have begun selling bioequivalents of CYCLOSPASMOL under the generic name "cyclandelate."

Ever since it began manufacturing CYCLOSPASMOL, Ives has used distinctive, colorful gelatin capsules as containers for the CYCLOSPASMOL powder. The 200 mg. capsule is pale blue; the 400 mg. capsule is red and blue. When appellees Premo Pharmaceutical Laboratories, Inc. ("Premo"), Inwood Laboratories, Incorporated ("Inwood"), and MD Pharmaceutical Company, Inc. ("MD") (collectively "the defendant manufacturers") began marketing cyclandelate, they intentionally chose to use gelatin capsules which were identical in color, shape, and size to those used by Ives even though scores of other colors, color combinations, and sizes were available.[4]

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3 Plaintiff seeks a wide range of remedies, including an injunction, the destruction of certain drug products and promotional materials, and damages. On remand, the district court will need to examine these issues in light of the remedy provisions of the Lanham Act, §§ 32-39, 15 U.S.C. §§ 1114-21.

4 Initially the capsules used by the defendant manufacturers bore no imprint of any kind, whereas the Ives' capsules were marked "Ives

Because CYCLOSPASMOL may only be dispensed by prescription, Ives has directed its CYCLOSPASMOL promotional efforts toward physicians, not patients. Some 230 "detail" men make periodic visits to physicians' offices on Ives' behalf, distributing samples and promotional material. Ives also places advertisements for CYCLOSPASMOL in professional journals read by physicians. The defendant manufacturers, on the other hand, have no similar network of detail men, and do not advertise routinely in professional magazines. They instead make their sales primarily through catalogs, which are distributed widely in the wholesale industry. Some of the catalogs contain charts which pair each generic product being offered with the name brand product for which it may be substituted and offer the generic product at a substantially lower price. The defendant wholesalers (Darby Drug Co., Inc. ("Darby"), Rugby Laboratories, Inc. ("Rugby"), and Sherry Pharmaceutical Co., Inc. ("Sherry")) purchase generic cyclandelate in capsules identical in appearance to those made by the defendant manufacturers and sell them at wholesale, primarily to physicians and pharmacies, at lower prices than those charged by Ives for its trademarked CYCLOSPASMOL.

Ives contends that appellees violated § 32 of the Lanham Act because their deliberate use of look-alike capsules and pro-substitution catalogs encouraged retail druggists to substitute generic cyclandelate illegally for CYCLOSPASMOL. In his first opinion, which denied

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4124" (200 mg.) and "Ives 4148" (400 mg.) in small letters. After this action was brought, Premo began placing the word "Premo" in small print on its capsules and Inwood likewise began labeling its capsules with the insignia "NDC 258" in small letters. In all other respects the CYCLOSPASMOL capsules sold by Ives and the cyclandelate capsules sold by defendants are identical.

plaintiff's motion for a preliminary injunction, Judge Nickerson reasoned that Ives' § 32 claim would only be viable if it could show "that defendants have conspired with the pharmacists or counseled or suggested that they disregard the doctors' orders."[5] 455 F. Supp. at 945. Finding that no such showing had been made, he rejected Ives' § 32 argument.

On appeal from this denial of preliminary relief we recognized that, although a classic case of retailer infringement occurs where a druggist illegally substitutes a generic drug for CYCLOSPASMOL prescribed by the doctor, a violation of § 32 for infringement also arises in the "intermediate" case when "the prescription permits substitution and the druggist fills it with defendant's [generic] product but names it Cyclospasmol." 601 F.2d at

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5 In New York State the pharmacist's freedom to fill brand name prescriptions with generic substitutes is circumscribed by statute. Prescription forms used by doctors bear two signature lines: one labeled "Dispense as Written," and one labeled "Substitution Permissible." N.Y. Educ. Law § 6810(6). If the physician signs over the line indicating "Dispense as Written," the pharmacist must follow his instructions exactly. If, on the other hand, the doctor signs over the line indicating "Substitution Permissible," the pharmacist must fill the prescription with the generic equivalent if the drug prescribed appears on a list prepared by the state. *Id.* at § 6816-a(1); N.Y. Pub. Health Law § 206(1)(o). If substitution is allowed by the physician but the prescribed drug does not appear on the state list (and CYCLOSPASMOL currently does not), the pharmacist is free to substitute or not as he wishes.

Unless the physician otherwise directs, pharmacists filling prescriptions with a generic drug must indicate on the prescription label the name of the manufacturer as well as the generic name of the drug, N.Y. Educ. Law § 6816-a(1)(c); on the other hand, if a trademarked drug such as CYCLOSPASMOL is involved, no indication of manufacturer is required on the label. Thus, a prescription for 200 mg. capsules of CYCLOSPASMOL, which has been signed by the physician over the "Substitution Permissible" line, may be filled in one of only two ways: (1) with CYCLOSPASMOL, in which case the pill bottle should bear a label reading CYCLOSPASMOL 200 mg."; or (2) with a generic cyclandelate such as that manufactured by Premo, in which case the label should read "Cyclandelate 200 mg. Premo."

636. We went on to question whether the district court's reading of § 32 had been too rigid:

> "We fear . . . that his [Judge Nickerson's] approach to the issue may have been unduly narrow. He referred to 'the knowing and deliberate instigation of such a practice' . . . and said that before 'passage of the Lanham Act the doctrine of contributory trademark infringement went no further than to hold one who actively shared a retailer's infringement, as in the case, for example, of one who places the infringing label on the articles before delivering them to the retailer.' . . . While such cases would surely constitute contributory infringement, they do not mark the limits of the doctrine. The authorities later reviewed indicate to us that *a manufacturer or wholesaler would be liable under § 32 if he suggested, even if only by implication, that a retailer fill a bottle with the generic capsules and apply Ives' mark to the label,* or continued to sell capsules containing the generic drug which facilitated this to a druggist whom he knew or had reason to know was engaging in the practices just described." 601 F.2d at 636 (emphasis supplied).

However, Judge Friendly concluded that on the record then before the court

> "the court was justified in concluding that Ives failed to adduce the quantum of proof necessary to require issuance of a temporary injunction for contributory infringement even on what we deem the proper standard of liability under § 32. Ives' proof was limited to 15 instances of improper substitution and defendants conceded only that the identity of color made this easier if a druggist were so inclined." *Id.*

On remand the district court heard Ives' evidence on the § 32 claim, and concluded that the factual showing necessary to prove plaintiff's case had once again not been made:

> "The court finds that defendants did not suggest, even by implication, that pharmacists fill bottles with the generic drug cyclandelate and apply the trademark Cyclospasmol. Nor did Ives show that defendants continued to sell the generic drug to pharmacists who defendants knew or had reason to know were engaging in such a practice." 488 F. Supp. at 397.

According to the district court, the new evidence introduced at trial on this point was limited to the following instances of mislabeling:

> "Some Ives test shoppers gave a prescription for Cyclospasmol signed on the line over 'substitution permissible' to forty-two pharmacists in New York selected from a list supplied by Ives and forty-one from a list of drug stores in Hayes Directory. Of the forty-two on the Ives list twenty-four dispensed Cyclospasmol, and eighteen dispensed the generic product. Six of those eighteen included the word Cyclospasmol on the label. Of the forty-one on the Hayes Directory list twenty-four dispensed Cyclospasmol and seventeen dispensed the generic product. Four of those seventeen included the word Cyclospasmol on the label.
>
> "Of the total of ten pharmacists who dispensed generic cyclandelate and also used the word Cyclospasmol on the label, four used the term 'generic Cyclospasmol' or 'Cyclospasmol generic' and one

> the term 'Cyclospasmol Gen.' Nine of the ten informed the person buying the capsules that the generic product had been dispensed.[*] Only one appears to have charged a higher 'brand' price. This evidence hardly justifies an inference that defendants' catalogs impliedly invited druggists to mislabel." *Id.*

In the district court's opinion, this frequent mislabeling of cyclandelate as CYCLOSPASMOL was occurring not because appellees had suggested that pharmacists do so, but rather because pharmacists "misunderstood the precise requirements of the New York Drug Substitution Law." *Id.* "[A]ny mislabeling stemmed from doubt as to the requirements of the generic drug law, not from inducement by defendants." *Id.* at 398.

DISCUSSION

Since the governing legal principles have already been set forth in Judge Friendly's opinion upon the earlier appeal, 601 F.2d 631 (2d Cir. 1979), we need not repeat them here. Applying those principles, we believe that the district court, in considering Ives' § 32 claim, erred upon remand in declining to give any weight to additional evidence offered by Ives indicating that appellees' use of identically-colored, look-alike drug capsules assisted druggists in labeling generic cyclandelate as Ives' trademarked product CYCLOSPASMOL, and that they could

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[6] This does not, however, mean that pharmacists as a rule spontaneously inform their customers whenever a generic substitution is made. The shoppers conducting the survey were instructed to inquire after receiving the filled prescription whether the generic substitute was in stock. Not surprisingly, a number of pharmacists responded by merely pointing to the generic with which the shopper's prescription had just been filled.

reasonably anticipate that the use of these capsules would have such an effect.

At the preliminary injunction hearing Ives introduced evidence of some 15 instances of illegal substitution by druggists of the generic drug cyclandelate for CYCLOSPASMOL after the latter had been prescribed, which we found insufficient to warrant reversal of the district court's denial of preliminary injunctive relief even though, taking into consideration the normal reluctance of any druggist to admit illegal conduct, it was surprising that Ives was able to produce as many such instances as it did. Recognizing this deficiency, Ives at trial introduced substantial additional evidence of "intermediate cases" of contributory infringement in which a druggist who was authorized to substitute the generic drug cyclandelate improperly used Ives' trademark CYCLOSPASMOL on the label.

In preparation for trial Ives carried out in a rigorous, impartial manner two series of drug shoppings at pharmacies. In each, the prescription reading "CYCLOSPASMOL—Substitution Permissible" was used. The first series consisted of having the prescriptions filled at 42 pharmacies from a list of drug stores believed to carry both CYCLOSPASMOL and cyclandelate. The second involved the submission of the same prescription to 41 pharmacies selected at random from the Hayes Directory of Pharmacies in New York State. The shoppings revealed that in 29% of the cases pharmacists mislabeled the generic product in some form (6 out of 18 pharmacists in the first shopping and 4 out of 17 in the second shopping).[7] In addition Ives adduced evidence that in 9 out of

[7] In his dissent Judge Mulligan asserts that the percentage figure should be 12% or "10 out of the entire sample of 83" rather than 29%. We disagree. The prescription used in the test was for CYCLOSPAS-

17 instances where patients retained bottles of prescribed generic cyclandelate the bottles had been mislabeled with the trademark name CYCLOSPASMOL in some form.

This pattern of illegal substitution and mislabeling in New York is precisely the sort of showing which we held would be probative of plaintiff's § 32 claim, stating that "a manufacturer or wholesaler would be liable under § 32 if he suggested, even if only by implication, that a retailer fill a bottle with the generic capsules and apply Ives' mark to the label." 601 F.2d at 636.

The additional evidence introduced by Ives at trial was clearly sufficient to establish a § 32 violation. By using capsules of identical color, size and shape, together with a catalog describing their appearance and listing comparative prices of CYCLOSPASMOL and generic cyclandelate, appellees could reasonably anticipate that their generic drug product would by a substantial number of druggists be substituted illegally for Ives' trademarked CYCLOSPASMOL or that bottles of their lower-priced product might be mislabeled as CYCLOSPASMOL, all to the druggists' economic advantage. This amounted to a

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MOL—Substitution Permissible." The objective of the study was to determine how many of the druggists who substituted the generic drug for CYCLOSPASMOL mislabeled the drug as CYCLOSPASMOL. Where a prescription was filled by the druggist with CYCLOSPASMOL itself, there obviously was no substitution and therefore no occasion to mislabel. Of the 35 instances where druggists substituted the generic drug there were 10 cases, or approximately 29%, in which the generic drug was mislabeled as CYCLOSPASMOL.

Premo also conducted a shopping survey of 50 pharmacies in preparation for trial, the results of which were introduced by stipulation. However, its survey was designed to refute allegations of illegal substitution rather than of improper labeling. The prescription used by Premo did not read "Substitution Permissible" but instead consisted of 25 prescriptions for CYCLOSPASMOL to be dispensed as written and 25 for cyclandelate to be dispensed as written. Nevertheless, 2 of the cyclandelate prescriptions were filled with bottles labeled "CYCLOSPASMOL."

suggestion, at least by implication, that the druggists take advantage of the opportunity to engage in such misconduct. By using look-alike capsules, appellees also reduced the likelihood that patients who were given a generic substitute would bring that fact to their doctor's (or their druggist's) attention. Similar activity has been enjoined as enabling druggists to defraud by palming off, *Upjohn Co. v. Schwartz,* 246 F.2d 254 (2d Cir. 1957); *Merrell-National Laboratories, Inc. v. Zenith Laboratories, Inc.,* 194 U.S.P.Q. 157, 159-60 (D.N.J. 1977); *E.R. Squibb & Sons, Inc. v. Premo Pharmaceutical Labs, Inc.,* 195 U.S.P.Q. 545 (S.D.N.Y. 1977); *Smith Kline & French Laboratories v. Broder,* 125 U.S.P.Q. 299 (S.D. Tex. 1959). We think appellees' activity should be enjoined as well.

The second premise of the district court's decision, that mislabeling occurs because of confusion rather than as a result of appellees' inducement, finds no support in the record. Indeed, it was the district court itself, in a short and casual exchange with a witness, which suggested that the mislabeling might result from pharmacists' thinking that CYCLOSPASMOL was a generic name rather than a trademark. The witness to whom he made the suggestion responded ambiguously, agreeing only that some pharmacists "may not be knowledgeable concerning the intricacies of the law." No evidence in the form of witnesses or surveys supporting the district court's suggestion was ever introduced at trial.

Against the absence of concrete evidence in the record supporting the district court's explanation for mislabeling we are now in possession of additional undisputed evidence, which we may judicially notice, suggesting that illegal substitution and mislabeling in New York are neither *de minimis* nor inadvertent. During the month of

Appendix D

May, 1980, six indictments were handed down in the New York City area alleging illegal substitution and mislabeling of generic cyclandelate in prescriptions requiring CYCLOSPASMOL.[8] These indictments, which reflect the grand jurors' views that reasonable grounds exist for charging the druggists with engagement in such illegal activities, is inconsistent with appellees' contention that mislabeling is rare or unintentional.

Appellees have not offered any persuasive evidence of a legitimate reason unrelated to CYCLOSPASMOL for using identically-colored, look-alike cyclandelate capsules instead of capsules of a different color, size or shape, which would minimize the practice of mislabeling, illegal substitution or confusion. Their arguments that look-alike capsules reduce patient confusion or anxiety in taking medication, enable doctors to communicate with

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8 The indictments in Bronx County are: *People v. Melrose Pharmacy, Inc.* (No. 1056-80); *People v. James Detura* (No. 1057-80); *People v. B & B Pharmacy, Inc.* (No. 1061-80); and *People v. Benjamin Bernstein* (No. 1062-80). The indictments in Kings County are: *People v. Pueblos Pharmacy, Inc.* (No. 1235-80); and *People v. Soel Melero* (No. 1236-80).

It is clear that under Rule 201 of the Federal Rules of Evidence judicial notice may be taken during an appeal. While it is somewhat unusual to take judicial notice of proceedings not directly involving the parties to an action, we believe that notice can properly be taken here where the facts being noticed are not in dispute, *In re Phillips*, 593 F.2d 356, 358 (8th Cir. 1979), the indictments themselves are part of the public record of a court, *Happy Investment Group v. Lakeworld Properties, Inc.*, 396 F. Supp. 175, 183 n.6 (N.D. Cal. 1975), and the appeal being heard is not from a criminal conviction, cf. *United States v. Fatico*, 458 F. Supp. 388, 395 (E.D.N.Y. 1978) (sentencing). See generally *United States v. Gonzalez*, 442 F.2d 698, 707 & n.4 (2d Cir. 1971); *United Keans of America v. McGovern*, 453 F. Supp. 836, 838-39 (N.D. Ala. 1978); *Insurance Co. of North America v. National Steel Service Center, Inc.*, 391 F. Supp. 512, 518 (N.D. W. Va. 1975).

In taking judicial notice of these indictments, we of course express no opinion as to the guilt or innocence of those indicted. We merely take judicial notice of the fact that several grand juries have examined evidence of illegal substitution and mislabeling and have found it sufficient to warrant indictment.

patients more easily concerning their medication, and aid in their identification of the drug in an emergency situation, are unconvincing. Although a few doctors and one pharmacist were of the view that patients receiving capsules in a size, shape or color different from the medication they usually receive may at first believe that they have the wrong drug, there was no evidence of any instances of such confusion, much less that it was widespread, or that it could not easily be cured by explaining the change to the patient, either voluntarily in accordance with accepted professional practice or in response to the patient's inquiry. Indeed one witness called by appellees (Lawler) testified that when the doctor or druggist explains that the different color or different shaped capsules are the same generic drug, patients do not refuse to accept and use it. There was no evidence that doctors or druggists refused to furnish such explanations. No patient testified to confusion or anxiety. Nor did appellees offer any survey of patients' attitudes with respect to the matter. On the contrary, there was evidence that many generic drugs (e.g., cyclandelate made by W. E. Hauck and so-called "branded" generics) are successfully marketed in capsules or tablets that do not copy Ives' trademarked product. Thus the inference is inescapable that appellees' use of identically-colored, shaped and sized capsules was in anticipation that they would successfully capitalize upon public acceptance of CYCLOSPASMOL by reason of the fact that at least a substantial number of druggists would either substitute the generic product illegally or mislabel it as CYCLOSPASMOL.

Finally, we note that the current use of look-alike capsules makes detection of mislabeling very unlikely. The doctors who write prescriptions for CYCLOSPASMOL rarely see the capsules which their patients end up receiv-

ing at the pharmacy. The patients who have those prescriptions filled will normally be lulled by the look-alike cyclandelate capsules into thinking that they are receiving what their doctor prescribed.

The simplest way to reduce illegal substitution and mislabeling is to require that cyclandelate be sold in capsules which do not resemble those used for CYCLOSPASMOL. This would alert the patient to the possibility that he has been given cyclandelate when his doctor specifically prescribed CYCLOSPASMOL, as well as put him on notice that the lower generic cost of the cyclandelate should have been charged if that is in fact what he has received. Such a change could be made by appellees without any appreciable difficulty or expense. It would also give Ives the protection to which it is entitled for its trademarked product.

The judgment of the district court is reversed and the case remanded for further proceedings consistent with the foregoing.

MULLIGAN, *Circuit Judge* (dissenting):

I would affirm on the opinion of Judge Nickerson on all of the issues presented on this appeal.[1] The majority

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1 The principal contention of Ives has been that the defendants violated section 43(a) of the Lanham Act. That issue has not been addressed by the majority. Suffice it to say that Ives' position that the generic drug supplied by the defendants was falsely described as comparable to or equivalent to Cyclospasmol was not supported on trial by any evidence and was abandoned on appeal. The contention that the use of identically colored capsules was a false designation of origin since the Ives' capsules had acquired a secondary meaning and that the color was not functional within *Pagliero v. Wallace China Co.*, 198 F.2d 339, 343 (9th Cir. 1943) was also found by the trial court to be without merit. While not reaching the § 43(a) violation the majority does disregard the finding of functionality.

here reverses solely on the ground that "undisputed evidence establishes a violation of § 32 of the Lanham Act." I respectfully disagree.

I have no dispute with the interpretation of § 32 of the Lanham Act which the majority purports to apply. Indeed it was set forth by Judge Friendly for a panel of this court of which I was a member, in Ives I, 601 F.2d 631 (1979). There is and can be no claim that Judge Nickerson misunderstood the law announced in our prior opinion.

With respect to the claimed § 32 Lanham Act violation, we found in Ives I, *supra,* that Ives had failed to adduce sufficient evidence of contributory infringement. "[T]he evidence of improper substitution was limited to 15 prescriptions. Discovery and trial might show that the practice was much more widespread or, on the other hand, as defendants suggest, that the pharmacies in question were known bad actors and few others engaged in such practices." *Id.* at 644. (The parties stipulated on trial that there were only 13 instances of such practices.)

Our inquiry then must focus upon whatever additional evidence was adduced by Ives on the trial. Ives submitted the results of some 83 test shoppings. Forty-two of these shoppings were conducted at pharmacies selected from a list prepared by Ives. One of Ives' own witnesses conceded that the selection of druggists by Ives' detail men for this list might have been tainted by knowledge of this litigation. While Ives would object to the characterization of these pharmacies as "bad actors," it would seem apparent that this list might be suspect and within the class of pharmacies to which we referred in our prior opinion. There is admittedly not a scintilla of evidence to suggest that the defendants sold to those pharmacies knowing or having reason to believe that illegal substitution or mislabeling had occurred. I therefore would con-

clude that under our prior opinion, the further evidence gleaned from such shoppings would hardly be probative of any violation by the defendants of Section 32. In any event the statement by the majority that Ives carried out in an "impartial manner" two series of drug shoppings is not entirely accurate.

Forty-one shoppings were impartially selected from a list contained in Hayes Druggist Directory, 1979 ed. Even taking the results of both series of shoppings, however, the results confirm Judge Nickerson's finding that there was no reasonable inference of an invitation by the defendants to mislabel. The testing hardly supports a finding that the practices condemned were "much more widespread" than those disclosed when this case first came to us in Ives I.

Only 10 out of the entire sample of 83 mislabeled the generic drug as Cyclospasmol. This amounts to some 12% of the sample and not the 29% estimated by the majority. More significantly, five of these ten included the word generic or its abbreviation before or after the word Cyclospasmol. Nine of the ten druggists advised the patient that they were dispensing the generic drug. Only one druggist out of 83 attempted an illegal substitution, charged a "higher" brand price and thus reaped any profit from a color confusion. These facts support rather than discredit the finding of the District Court that druggists were confused with respect to the labeling requirements of the new generic drug law and were not motivated by profit considerations. Any pharmacist who intended to mislabel would simply place the name Cyclospasmol on the label and charge a higher price. He would hardly put generic on the label and inform the customer that he was receiving a generic. In sum, the additional

evidence adds nothing of substance to the record previously before this court.[2]

It is also significant that the defendants did not employ "detail" men who contacted druggists and thus were in a position to encourage substitution or mislabeling.[3] This fact completely distinguishes this case from *Upjohn Co. v. Schwartz*, 246 F.2d 254 (2d Cir. 1957) which is relied upon in the majority opinion. That case involved the use of look alike products but there was also proof that the defendant's salesmen had contacted druggists for the very purpose of encouraging substitution. No such evidence exists here.

The sampling by Ives of druggists on the Sec. 32 issue was in any event inadequate. On the secondary meaning question (§ 43(a)) which involved a survey of doctors, a list of some 12,000 physicians was assembled and a random selection of names was made in twenty randomly selected geographical areas throughout the country. On the Section 32 contributory infringement issue, however, only 83 druggists located in the State of New York and only half randomly selected, were questioned. There are some 3,000 pharmacists in the State of New York alone. The record indicates that Cyclospasmol is prescribed to some 100,000 patients nationwide. A testing of some 83 druggists in one state does not present a sufficient basis after our remand for the injunctive relief sought here particularly in light of the results obtained.

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2 An Ives witness, the President of the New York State Pharmaceutical Society, testified that he knew personally of no illegal substitution of generic for brand name drugs, and in answer to a question from the court stated that he did not believe the practice was widespread.

3 Ives, on the other hand, employs detail men who personally visit pharmacists and admittedly know which of them have a proclivity for illegal substitution.

Appendix D

In an effort to bolster what I believe is a weak record, the majority takes judicial notice of the fact that subsequent to the trial in this case six indictments have been handed down in the New York City area alleging illegal substitution and mislabeling of generic cyclandelate in prescriptions requiring Cyclospasmol. This we are told constitutes "additional undisputed evidence suggesting that illegal substitution and mislabeling in New York are neither *de minimis* nor inadvertent." Of course it is not disputed that the indictments have been filed but the record does not show any convictions. Six indictments are certainly not proof of any illegality and cannot reasonably be described as undisputed evidence of widespread or deliberate substitution and mislabeling even by the druggists much less by the defendant manufacturers here. If pharmacists are violating state laws which provide criminal sanctions, they should be punished. The criminal actions commenced if anything should discourage unethical pharmacists, and if convictions ensue even the *de minimis* violations adduced on this trial would be further reduced.

Admittedly there has been an imitation of color and capsule and the use of catalogues displaying both the generic and brand name drugs. There was, however, evidence that the catalogue juxtaposition of the drugs was a trade practice.[4]

The majority also contends that the appellees have not offered any "persuasive" evidence of a legitimate reason

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[4] Two defense witnesses, Sperber and Blackman testified that it was common in the industry to list the genric drug next to the brand name drug. In addition, Mr. Lowenkron, a witness for Ives, testified that druggists and doctors refer to drugs by the brand name. Thus, it would seem that juxtaposition of the generic and brand name drug would be imperative for generic manufacturers to compete effectively. See *Pagliero v. Wallace China Co., supra,* 198 F.2d at 343.

unrelated to Cyclospasmol for using identically-colored, look-alike capsules instead of those of a different color, size or shape. However, the trial court which heard the evidence found that the colors were functional in several respects. The court found that many elderly patients associate the appearance of their medication with its therapeutic effects. The court credited testimony that some elderly patients refuse to take equivalent drugs of a different color despite explanations of equivalence by their physicians while others do eventually accept it but experience confusion and anxiety. 488 F.Supp. at 389, 399. The majority does not characterize this finding or other evidence of functionality discussed in the opinion below[5] as "clearly erroneous." This finding was based on the testimony of three physicians and the Chief Pharmacist of a hospital. There is no reason to require the direct evidence of such patients as the majority suggests. Judge Nickerson's findings of fact based upon the testimony of witnesses who appeared before him cannot be disregarded by this court. See, e.g., *Master Shipping Agency, Inc. v. M.S. Farida,* 571 F.2d 131 (2d Cir. 1978).

In sum I am persuaded that Ives has failed on trial to adduce any evidence of substance which would support a finding of a Section 32 violation. I would affirm.

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5 Other evidence which supported Judge Nickerson's finding of functionality of the color included: testimony by physicians that they often give their patients color coded charts to help the patients avoid confusion between several drugs; testimony that color is useful in identifying drug overdoses in emergencies; and evidence which showed that some hospitals and pharmacies refused to purchase green cyclandelate capsules because of a potential for confusion. *Ives Laboratories, Inc. v. Darby Drug Co., Inc., supra,* 488 F.Supp. at 399.

Appendix D

UNITED STATES COURT OF APPEALS
SECOND CIRCUIT

At a Stated Term of the United States Court of Appeals, in and for the Second Circuit, held at the United States Courthouse, in the City of New York on the twenty-third day of March, One Thousand Nine Hundred and Eighty-One.

Present:

HONORABLE J. EDWARD LUMBARD,

HONORABLE WALTER R. MANSFIELD,

HONORABLE WILLIAM H. MULLIGAN,

Circuit Judges.

FILED MAR. 23, 1981
A. Daniel Fusaro, Clerk

Dkt. No. 80-7314

IVES LABORATORIES, INC.,
Plaintiff-Appellant,

-against-

DARBY DRUG CO., INWOOD LABORATORIES INCORPORATED, MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,
Defendants-Appellees.

Appendix D

Our opinion in the above is corrected as follows:

Slip. Op. page 967, line 12: The word "appellees" is changed to "appellant".

s/ J. Edward Lumbard
J. Edward Lumbard, U.S.C.J.

s/ Walter R. Mansfield
Walter R. Mansfield, U.S.C.J.

s/ William H. Mulligan
William H. Mulligan, U.S.C.J.

APPENDIX E — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT, *IVES LABORATORIES, INC. v. DARBY DRUG CO., INC.*, (2D CIR., FEB. 25, 1981)

UNITED STATES COURT OF APPEALS
SECOND CIRCUIT

No. 80-7314

At a stated term of the United States Court of Appeals, in and for the Second Circuit, held at the United States Court House, in the City of New York, on the 25th day of February, one thousand nine hundred and eighty-one.

IVES LABORATORIES, INC.,
Plaintiff-Appellant,

-against-

DARBY DRUG CO., INC., INWOOD LABORATORIES INCORPORATED, MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,
Defendants-Appellees.

Filed
Feb. 25, 1981

A petition for rehearing containing a suggestion that the action be reheard in banc having been filed herein by counsel for the defendants-appellees, Darby Drug Co. Inc., et al,

Upon consideration by the panel that heard the appeal, it is

Appendix E

Ordered that said petition for rehearing is DENIED.

It is further noted that the suggestion for rehearing in banc has been transmitted to the judges of the court in regular active service and to any other judge on the panel that heard the appeal and that no such judge has requested that a vote be taken thereon.

s/ A. Daniel Fusaro
A. Daniel Fusaro,
Clerk

APPENDIX F — MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK, *IVES LABORATORIES, INC. v. DARBY DRUG CO., INC.*, ___ F. SUPP. ___, NO. 78 C 372 (E.D.N.Y. MAY 12, 1981)

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

78 C 372

IVES LABORATORIES, INC.,

Plaintiff,

-against-

DARBY DRUG CO., INC., INWOOD LABORATORIES, INC., MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,

Defendants.

COOPER, DUNHAM, CLARK, GRIFFITH & MORAN
(Marie V. Driscoll, Esq., of counsel)
New York, New York
for Ives Laboratories, Inc.

KIRSCHSTEIN, KIRSCHSTEIN, OTTINGER & COBRIN, P.C.
(Peter T. Cobrin, Esq., of counsel)
New York, New York
for Premo Pharmaceutical Laboratories, Inc.

Appendix F

SALON, MARROW AND DYCKMAN
(Robert V. Marrow, Esq., of counsel)
New York, New York
for Darby Drug Co., Inc., MD Pharmaceutical Laboratories, Inc., Rugby Laboratories, Inc., and Sherry Pharmaceutical Co., Inc.

BASS, ULMAN & LUSTIGMAN
(Steven R. Trost, Esq., of counsel)
New York, New York
for Inwood Laboratories, Inc.

NICKERSON, District Judge

Plaintiff Ives Laboratories brought suit in this court alleging that defendants violated Sections 32 and 43(a) of the Lanham Act, 15 U.S.C. §§1114 and 1125(a), by manufacturing and distributing a generic drug—cyclandelate— using capsules identical in color, shape, and size to those used by plaintiff in its equivalent trademarked product—Cyclospasmol. This court dismissed the action after a bench trial. On January 8, 1981 the Court of Appeals reversed this court's judgment and remanded for further proceedings consistent with its opinion. Plaintiff now moves for entry of an order on the mandate of the Court of Appeals.

I

Defendants urge the court not to restrain them from selling cyclandelate in blue or blue and red capsules resembling those used for Cyclospasmol. Instead, they ask the court merely to order them to place on or with every container of their cyclandelate products an appropriate warning against labelling the products as Cyclospasmol.

Appendix F

This court reads the majority opinion of the Court of Appeals as requiring this court to grant a permanent injunction giving plaintiff a monopoly over the colors blue and a combination of blue and red for capsules of the same shape and size as those used by plaintiff to sell Cyclospasmol. Certainly a mere notice to pharmacists would not meet the conditions set by the majority opinion of the Court of Appeals. This court's views of the merits of the matter are now irrelevant. The opinion of the Court of Appeals is binding. The injunction to be issued will restrain defendants from selling cyclandelate in capsules that are confusingly similar in color, shape, and size to those now used by plaintiff.

II

Plaintiff asks that the court order defendants to deliver to plaintiff for destruction all the blue and blue and red capsules containing cyclandelate in their possession. Plaintiff also seeks an order directing a recall by defendants of all such capsules sold to customers after January 8, 1981, the date of the Court of Appeals opinion, and a delivery of those capsules to plaintiff for destruction.

Under 15 U.S.C. §1118, where a violation of trademark rights has been established, the court "may order" all receptacles "bearing the registered mark" or any "colorable imitation thereof" to be "delivered up and destroyed."

The court will direct defendants to recall the capsules sold to defendants' customers since January 8, 1981. *Perfect Fit Industries, Inc. v. Acme Quilting Co., Inc.*, Nos. 80-7489, 7585, 7587 (2d Cir. April 13, 1981). Since the defendants' capsules do not bear plaintiff's mark Cyclospasmol, §1118 would not seem to authorize their delivery to plaintiff for destruction. But even if

in equity the court has such power, the court must bear in mind the Second Circuit's admonition that the court should "shape the remedy so as to do as little injury to the defendant as is necessary in order to insure adequate protection to the plaintiff." *Upjohn Company v. Schwartz*, 246 F.2d 254, 262 (2d Cir. 1957) *quoting Artype, Inc. v. Zappulla*, 228 F.2d 695, 698 (2d Cir. 1956) (L. Hand, J.). Plaintiff will be adequately protected if defendants cease to put cyclandelate in capsules of the same color, size, and shape as plaintiff. The cyclandelate can be recovered and placed in capsules of different colors, and the blue and blue and red capsules may be utilized for other products.

III

Plaintiff also seeks damages, profits, and costs. The provisions of 15 U.S.C. §1117 recite that a successful plaintiff in a trademark action "shall be entitled, subject to the provisions of sections 1111 and 1114 of this title, and subject to the principles of equity, to recover (1) defendant's profits, (2) any damages sustained by the plaintiff, and (3) the costs of the action." Since the Court of Appeals has directed in its mandate that plaintiff recover costs the court will include such a provision in the order.

The court need not award profits and damages if an injunction will satisfy the equities of the case. *Carl Zeiss Stiftung v. Veb Carl Zeiss Jena*, 433 F.2d 686, 706-07 (2d Cir. 1970), *cert. denied*, 403 U.S. 905 (1971); *Grotrian, Helfferich, Schulz, TH. Steinwag Nachf v. Steinway & Sons*, 523 F.2d 1331, 1344 (2d Cir. 1975). But where the infringer acted with "the deliberate intent to cause confusion, mistake or to deceive purchasers; in other words, to purposely palm off the infringer's goods as those of the infringed," the court is required to award damages and profits. *Carl Zeiss Stiftung v. Veb Carl Zeiss Jena, supra*, 433 F.2d at 707.

The opinion of the Court of Appeals in the present case finds such a deliberate intent. Accordingly, plaintiff may recover its damages and defendants' profits to the extent they are proven. *Perfect Fit Industries, Inc. v. Acme Quilting Co.*, 618 F.2d 950, 955 (2d Cir. 1980).

IV

Plaintiff seeks to recover attorney fees pursuant to the last sentence of 18 U.S.C. §1117 which reads, "The court in exceptional cases may award reasonable attorney fees to the prevailing party." According to the legislative history attorney fees should be awarded to plaintiffs where "the acts of infringement can be characterized as 'malicious,' 'fraudulent,' 'deliberate,' or 'willful.'" S. Rep. No. 93-1400, 93rd Cong., 2nd Sess. *reprinted in* [1974] U.S. Code Cong. & Ad. News 7132, 7133.

Certainly in the light of the dissenting opinion of Judge Mulligan in the present case it cannot be said that defendants asserted their defenses in bad faith or that a gross injustice would be done if attorney fees were denied. Under the circumstances this court deems this case not to be "exceptional" and therefore will not award attorney fees.

An order is entered with this memorandum.

Dated: Brooklyn, New York
May 12, 1981

s/ Eugene H. Nickerson
Eugene H. Nickerson, U.S.D.J.

Appendix F

The Clerk shall make copies of this Memorandum and serve it upon the parties.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

78 C 372

IVES LABORATORIES, INC.,

Plaintiff,

-against-

DARBY DRUG CO., INC., INWOOD LABORATORIES, INC., MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,

Defendants.

ORDER

Plaintiff having appealed to the United States Court of Appeals for the Second Circuit from the judgment entered on April 29, 1980, and the Court having issued a decision on January 8, 1981 reversing the judgment of this court and remanding the case, and defendants' petition for rehearing and rehearing en banc having been denied by the Court on February 25, 1981, and the mandate of the Court having been transmitted and filed in this court on March 10, 1981, in compliance with that mandate it is on motion of plaintiff,

ORDERED, ADJUDGED, AND DECREED:

1. Defendants Darby Drug Co., Inc., Inwood Laboratories, Inc., MD Pharmaceutical Company, Inc. Premo Pharmaceutical Laboratories, Inc., Rugby Laboratories, Inc., and Sherry Pharmaceutical Co., Inc., their officers, agents, servants, employees and all those holding by, through or under them or any of them, and all persons acting in concert or participation with them, including all parents and subsidiary corporations, and successors and assigns, are permanently restrained and enjoined from manufacturing for sale, selling, offering for sale, advertising or promoting the drug cyclandelate in capsules confusingly similar to plaintiff's present Cyclospasmol capsules by reason of their blue or blue and red colors and their size and shape.

2. Upon receiving notice of this judgment each defendant shall make an accurate inventory under oath of all cyclandelate in their possession or under their control in such blue or blue and red capsules as well as any printed material referring to or describing the appearance of said capsules and shall, within 15 days of receipt of notice of this judgment, deliver the inventory list to plaintiff in care of Egon Berg, Esq., American Home Products Corporation, 685 Third Avenue, New York, New York 10017.

3. Defendants shall, not later than 15 days of receipt of the notice of this judgment, at their expense, deliver to an independent mailing concern to be designated by plaintiff, pre-addressed envelopes containing the names and addresses of all wholesalers, distributers, jobbers, pharmacies, and any person, firm or corporation whatsoever to whom defendants, their agents, servants, employees, or attorneys distributed, shipped, offered for sale, or sold, blue or blue and red cyclandelate

capsules after January 8, 1981 so that such mailing concern may mail by first class mail and at defendants' expense, letters notifying those to whom defendants distributed, shipped, offered for sale, or sold blue or blue and red cyclandelate capsules after January 8, 1981 that the capsules may not be used to fill physicians' prescriptions for Cyclospasmol and requesting that all such blue or blue and red capsules be sent immediately to defendants. Defendants shall offer monetary credit for such products, and shall grant such credit for products sent them.

4. Within 10 days after receipt of notice of this judgment defendants shall each make a draft of the notification letter required by paragraph 3 available to plaintiff, and shall advise plaintiff of the number of envelopes to be mailed by the mailing concern, provided that it undertakes in writing to maintain the identity of the names and addresses on the envelopes confidential and not to disclose such identity, directly or indirectly, to plaintiff or any of its agents, servants, attorneys or employees and that the envelopes contain no marking other than the names and addresses and a return address, except that the envelopes shall contain on the front face the notation "IMPORTANT NOTICE" in prominent and readable block letters and shall contain nothing other than the notification.

5. Plaintiff shall recover from the defendants its damages sustained and the defendants' profits derived by reason of defendants' sale of cyclandelate in blue or blue and red capsules simulating the appearance of plaintiff's capsules containing Cyclospasmol. The issues as to the amount of damages and profits shall be tried before this court.

6. Plaintiff shall have judgment against defendants for costs in the Court of Appeals and in this court up to and including the entry of judgment. The costs are to be taxed by the Clerk.

Plaintiff shall submit a verified bill of costs within 20 days after entry of this judgment. This court reserves for further consideration all questions pertaining to damages and profits and to costs relating to proceedings to determine damages and profits.

7. This court retains jurisdiction to assure compliance by defendants and to consider damages and profits and further costs.

Enter.

Dated: Brooklyn, New York
May 12, 1981

s/ Eugene H. Nickerson
Eugene H. Nickerson, U.S.D.J.

The Clerk shall make copies of this Order and serve it upon the parties.

APPENDIX G — ARTICLE I, SECTION 8, CLAUSE 8 OF THE CONSTITUTION OF THE UNITED STATES

"Section 8. The Congress shall have Power . . .

* * *

To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries; . . ."

APPENDIX G — THE FIRST AMENDMENT TO THE CONSTITUTION OF THE UNITED STATES

"AMENDMENT [I]

Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances."

APPENDIX G — §32 OF THE LANHAM ACT, 15 U.S.C. §1114

"§1114. Remedies; infringement; innocent infringement by printers and publishers

(1) Any person who shall, without the consent of the registrant—

(a) use in commerce any reproduction, counterfeit, copy, or colorable imitation of a registered mark in connection with the sale, offering for sale, distribution, or advertising of any goods or services on or in connection with which such use is likely to cause confusion, or to cause mistake, or to deceive; or

(b) reproduce, counterfeit, copy or colorably imitate a registered mark and apply such reproduction, counterfeit, copy, or colorable imitation to labels, signs, prints, packages, wrappers, receptacles or advertisements intended to be used in commerce upon or in connection with the sale, offering for sale, distribution, or advertising of goods or services on or in connection with which such use is likely to cause confusion, or to cause mistake, or to deceive.

shall be liable in a civil action by the registrant for the remedies hereinafter provided. Under subsection (b) of this section, the registrant shall not be entitled to recover profits or damages unless the acts have been committed with knowledge that such imitation is intended to be used to cause confusion or to cause mistake, or to deceive.

(2) Notwithstanding any other provision of this chapter, the remedies given to the owner of the right infringed shall be limited as follows: (a) Where an infringer is engaged solely in the business of printing the mark for others and establishes that he was an innocent infringer the owner of the right infringed shall be entitled as against such infringer only to an injunction against future printing; (b) where the infringement complained of is contained in or is part of paid advertising matter in a newspaper, magazine, or other similar periodical the remedies of the owner of the right infringed as against the publisher or distributor of such newspaper, magazine, or other similar periodical shall be confined to an injunction against the presentation of such advertising matter in future issues of such newspapers, magazines, or other similar periodical: *Provided,* That these limitations shall apply only to innocent infringers; (c) injunction relief shall not be available to the owner of the right infringed in respect of an issue of a newspaper, magazine, or other similar periodical containing infringing matter when restraining the dissemination of such infringing matter in any particular issue of such periodical would delay the delivery of such issue after the regular time therefor, and such delay would be due to the method by which publication and distribution of such periodical is customarily conducted in accordance with sound business practice, and not to any method or device adopted for the evasion of this section or to prevent or delay the issuance of an injunction

or restraining order with respect to such infringing matter. July 5, 1946, c. 540, Title VI, §32, 60 Stat. 437; Oct. 9, 1962, Pub. L. 87-772, §17, 76 Stat. 773."

APPENDIX G — §43(a) OF THE LANHAM ACT, 15 U.S.C. §1125(a)

"§1125. False designations of origin and false descriptions forbidden

(a) Any person who shall affix, apply, or annex, or use in connection with any goods or services, or any container or containers for goods, a false designation of origin, or any false description or representation, including words or other symbols tending falsely to describe or represent the same, and shall cause such goods or services to enter into commerce, and any person who shall with knowledge of the falsity of such designation or origin or description or representation cause or procure the same to be transported or used in commerce or deliver the same to any carrier to be transported or used, shall be liable to a civil action by any person doing business in the locality falsely indicated as that of origin or in the region in which said locality is situated, or by any person who believes that he is or is likely to be damaged by the use of any such false description or representation.

(b) Any goods marked or labeled in contravention of the provisions of this section shall not be imported into the United States or admitted to entry at any customhouse of the United States. The owner, importer, or consignee of goods refused entry at any customhouse under this section may have any recourse by protest or appeal that is given under the customs revenue laws or may have the remedy given by this

chapter in cases involving goods refused entry or seized.

July 5, 1946, c. 540, Title VIII, §43, 60 Stat. 441."

APPENDIX G — NEW YORK EDUCATION LAW §§6810; 6815(2)(h), (j); 6816, 6816-a (McKINNEY'S SUPP. 1981)

"§6810. Prescriptions

1. No drug for which a prescription is required by the provisions of the Federal Food, Drug and Cosmetic Act[1] or by the commissioner of health shall be distributed or dispensed to any person except upon a prescription written by a person legally authorized to issue such prescription. Such drug shall be compounded or dispensed by a licensed pharmacist, and no such drug shall be dispensed without affixing to the immediate container in which the drug is sold or dispensed a label bearing the name and address of the owner of the establishment in which it was dispensed, the date compounded, the number of the prescription under which it is recorded in the pharmacist's prescription files, the name of the prescriber, the name and address of the patient, and the directions for the use of the drug by the patient as given upon the prescription. The prescribing and dispensing of a drug which is a controlled substance shall be subject to additional requirements provided in article thirty-three of the public health law. The words 'drug' and 'prescription required drug' within the meaning of this article shall not be construed to include soft or hard contact lenses, eyeglasses, or any other device for the aid or correction of vision.

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1. 21 U.S.C.A. §301 et seq.

2. A prescription may not be refilled unless it bears a contrary instruction and indicates on its face the number of times it may be refilled. A prescription may not be refilled more times than allowed on the prescription. The date of each refilling must be indicated on the original prescription. Prescriptions for controlled substances shall be refilled only pursuant to article thirty-three of the public health law.

3. A copy of a prescription for a controlled substance shall not be furnished to the patient but may be furnished to any licensed practitioner authorized to write such prescription. Copies of other prescriptions shall be furnished to the patient at his request, but such copies are issued for the informational purposes of the prescribers only, and shall be so worded.

4. Oral prescriptions for controlled substances shall be filled pursuant to article thirty-three of the public health law. A pharmacist may fill an oral prescription for a drug, other than a controlled substance, made by a practitioner legally authorized to prescribe drugs. An oral authorization for the refill of a prescription, other than a prescription for a controlled substance, may be made by a practitioner legally authorized to prescribe drugs. The pharmacist receiving such oral authorization for the refill of a prescription shall write on the reverse side of the original prescription the date, time, and name of the practitioner authorizing the refill of the prescription.

5. Records of all prescriptions filled or refilled shall be maintained for a period of at least five years and upon request made available for inspection and copying by a representative of the department. Such records shall indicate date of filling or refilling, doctor's name, patient's name and address and the name or initials of the pharmacist who prepared, compounded, or dispensed the prescription. Records of prescriptions for controlled substances shall be maintained pursuant to requirements of article thirty-three of the public health law.

6. (a) Every prescription written in this state by a person authorized to issue such prescription shall be on prescription forms containing two lines for the prescriber's signature. There shall be a signature line in the lower right hand corner of the prescription form beneath which shall be clearly imprinted the words 'substitution permissible'; there shall be a signature line in the lower left hand corner of the prescription form beneath which shall be clearly imprinted the words 'dispense as written'. The prescriber's signature on either signature line shall validate the prescription and shall designate approval or disapproval of substitution by a pharmacist of a drug product pursuant to paragraph (*o*) of subdivision one of section two hundred six of the public health law. Imprinted conspicuously on the prescription forms shall be the words: 'This prescription will be filled generically unless physician signs on line stating "dispense as written".'

(b) If the prescriber designates approval of substitution he shall inform the patient that the pharmacist will substitute a drug product pursuant to paragraph (*o*) of subdivision one of section two hundred six of the public health law.

(c) The provisions of this subdivision shall not apply to a hospital as defined in article twenty-eight of the public health law.

Added L.1972, c. 881, §5; amended L.1977, c. 776, §2.

§6815. Adulterating misbranding and substituting

* * *

2. Misbranded and substituted drugs and devices. A drug or device shall be deemed to be misbranded:

* * *

h. (1) If it is a drug and its container is so made, formed or filled as to be misleading; (2) if it is an imitation of another drug; (3) if it is offered for sale under the name of another drug; or (4) if it bears a copy, counterfeit, or colorable imitation of the trademark, label, container or identifying name or design of another drug.

* * *

j. Except as required by article thirty-three of the public health law, the labeling provisions of this article shall not apply to the compounding and dispensing of drugs on the written prescription of a physician, a dentist, a podiatrist or a veterinarian, which prescription when filled shall be kept on file for at least five years by the pharmacist or druggist. Such drug shall bear a label containing the name and place of business of the dispenser, the serial number and date of the prescription, directions for use as may be stated in the prescription, name and address of the patient and the name of the physician or other practitioner authorized by law to issue the prescription. In addition, such label shall contain the proprietary or brand name of the drug and, if applicable, the strength of the contents, unless the person issuing the prescription explicitly states on the prescription, in his own handwriting, that the name of the drug and the strength thereof should not appear on the label.

As amended L.1972, c. 881, §6; L.1973, c. 752, §1.

§6816. Omitting to label drugs, or labeling them wrongly

1. a. Any person, who, in putting up any drug, medicine, or food or preparation used in medical practice, or making up any prescription, or filling any order for drugs, medicines, food or preparation puts any untrue label, stamp or other designation of contents upon any box, bottle or

other package containing a drug, medicine, food or preparation used in medical practice, or substitutes or dispenses a different article for or in lieu of any article prescribed, ordered, or demanded, except where required pursuant to section sixty-eight hundred sixteen-a of this article, or puts up a greater or lesser quantity of any ingredient specified in any such prescription, order or demand than that prescribed, ordered or demanded, or otherwise deviates from the terms of the prescription, order or demand by substituting one drug for another, except where required pursuant to section sixty-eight hundred sixteen-a of this article, is guilty of a misdemeanor; provided, however, that except in the case of physicians' prescriptions, nothing herein contained shall be deemed or construed to prevent or impair or in any manner affect the right of any apothecary, druggist, pharmacist or other person to recommend the purchase of an article other than that ordered, required or demanded, but of a similar nature, or to sell such other article in place or in lieu of an article ordered, required or demanded, with the knowledge and consent of the purchaser. Upon a second conviction for a violation of this section the offender must be sentenced to imprisonment, for a term of not less than ten days nor more than one year, and to the payment of a fine of not less than ten dollars nor more than five hundred dollars. The third conviction of a violation of any of the provisions of this section, in addition to rendering the offender liable to the

penalty prescribed by law for a misdemeanor, shall forfeit any right which he may possess under the law of this state at the time of such conviction, to engage as proprietor, agent, employee or otherwise, in the business of an apothecary, pharmacist, or druggist, or to compound, prepare or dispense prescriptions or orders for drugs, medicines or foods or preparations used in medical practice; and the offender shall be by reason of such conviction disqualified from engaging in any such business as proprietor, agent, employee or otherwise or compounding preparing or dispensing medical prescriptions or orders for drugs, medicines, or foods or preparations used in medical practice.

b. The provisions of this section shall not apply to the practice of a practioner who is not the proprietor of a store for the dispensing or retailing of drugs, medicines and poisons, or who is not in the employ of such a proprietor, and shall not prevent practitioners from supplying their patients with such articles as they may deem proper, and except as to the labeling of poisons shall not apply to the sale of medicines or poisons at wholesale when not for the use or consumption by the purchaser; provided, however, that the sale of medicines or poisons at wholesale shall continue to be subject to such regulations as from time to time may be lawfully made by the board of pharmacy or by any competent board of health.

c. The provisions of this section shall not apply to a limited pharmacy which prepares a formulary containing the brand names and the generic names of drugs and of manufacturers which it stocks, provided that it furnishes a copy of such formulary to each physician on its staff and the physician signs a statement authorizing the hospital to supply the drug under any generic or nonproprietary name listed therein and in conformity with the regulations of the commissioner of education.

2. For the purposes set forth in this section, the terms prescription, order or demand shall apply only to those items subject to provisions of subdivision one of section sixty-eight hundred ten of this chapter. The written order of a physician for items not subject to provisions of subdivision one of section sixty-eight hundred ten of this chapter shall be construed to be a direction, a fiscal order or a voucher.
As Amended L.1976, c. 76, §14; L.1977, c. 776, §3.

* * *

§6816-a. When substitution is required.

1. A pharmacist shall substitute a less expensive drug product containing the same active ingredients, dosage form and strength as the drug product prescribed, ordered or demanded, provided that the following conditions are met:

Appendix G

(a) The prescription is written on a form which meets the requirements of subdivision six of section sixty-eight hundred ten of this article and the prescriber places his signature above the words, 'substitution permissible', or in the case of oral prescriptions, the prescriber must expressly state that substitution shall be permitted; and

(b) The substituted drug product is contained in the list of drug products established pursuant to paragraph (*o*) of subdivision one of section two hundred six of the public health law; and

(c) The pharmacist shall indicate on the label affixed to the immediate container in which the drug is sold or dispensed the name and strength of the drug product and its manufacturer unless the prescriber specifically states otherwise. The pharmacist shall record on the prescription form the brand name or the name of the manufacturer of the drug product dispensed.

2. In the event a patient chooses to have a prescription filled by an out of state dispenser, the laws of that state shall prevail.
Added L.1977, c. 776, §4."

APPENDIX G — NEW YORK PUBLIC HEALTH LAW, §206(1)(o) (McKINNEY'S SUPP. 1981)

"§206. Commissioner; general powers and duties

1. The commissioner shall:

* * *

(o) establish and publish a list of drug products, each of which shall meet the following conditions:

(1) The drug product has been certified or approved by the commissioner of the Federal Food and Drug Administration as being safe and effective for its labeled indications for use, and a new-drug application or an abbreviated new-drug application approved pursuant to the Federal Food, Drug, and Cosmetic Act is held for such drug products; and

(2) The commissioner of the Federal Food and Drug Administration has:

(i) not proposed or promulgated a regulation to establish a bioequivalency requirement for such drug product, or

(ii) proposed a regulation to establish a bioequivalency requirement for such drug product and subsequently has determined not to promulgate such regulation for such drug product, or

(iii) promulgated a regulation to establish a bioequivalency requirement for such drug product and has approved a supplemental application that provides evidence that the drug product meets the bioequivalency requirement."